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Nanomaterials patenting in Brazil: some considerations for the national regulatory framework

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Abstract Progress on the development of nanotechnology has led to a number of initiatives which serve to normalize activities in this area. Among emerging technologies, nanotechnology is one of the most prominent, and it raises high expectations in a wide range of areas affecting daily life. The risks to human health, the pathways of exposure to nanomaterials, and occupational safety are recent issues which require more attention. The study was performed on nanopatents by collecting, processing and analyzing information extracted from specialized patent databases covering the period from 1991 to 2011, totalling 1,343 patents and representing 36 countries. These patents were classified by the International Patent Classification, using the methodology proposed in a study published by Organization for Economic Co-operation and Development, which resulted in six groups of patents, distributed as follows: nanomaterials (40.3 %), medicine and biotechnology (26.6 %), measurement and production (10 %), electronics (2.7 %), energy and the environment (2.2 %), and optical electronics (1 %). Around 17 % of the patents in question did not fall into the adopted classification. The aim of this paper is to analyze the main trends of patenting related to nanotechnology, its development and environmental implications. An additional goal is to assist policy-makers to adjust the regulatory framework on nanotechnology, and to make recommendations for governments, industry, and national organizations, on creating specific subsidies for regulatory framework in Brazil.

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Introduction

The development of nanotechnology has been hailed as a new technological revolution, due to its enormous innovation potential for industrial and economic development (Medeiros et al. 2006; Fernandes and Filgueiras 2008; Robinson 2009; Allarakhia and Walsh 2012).

Brazil has increasingly been investing in nanotechnology, since this new technology lends itself to methodological adoption worldwide (Meyer and Persson 1998; Chamas 2008; Rossi-Bergmann 2008; Zanetti-Ramos and Creczynski-Pasa 2008). The countries that invest most in nanotechnology are the United States of America, Japan and some European countries, but countries like Brazil, Russia, India, China and South Africa (BRICs) have made significant investments in the sector in recent years (Salerno et al. 2008). Estimates of investment in the world market for industrial materials, products and processes based on nanotechnology are around one trillion dollars. This voluminous production will be distributed over practically all economic sectors, because nanotechnology will affect a great number of industrial products and processes in all areas, besides creating new service activities (Rediguieri 2009; Robinson 2009).

A patent document contains dozens of items for analysis; some are prepared, connotating they are uniform in semantics and in format across patents in such aspects as patent number, filing date, or assignees; some are formless, meaning they are free texts of various lengths and contents, such as claims, abstracts, or descriptions of the invention (Tseng et al. 2007; He and Loh 2010). The importance of patent data as a source for technology and competitive intelligence has been acknowledged for a long time. Patent documents also offer competitive intelligence to support a company's business decisions. In order for a patent to protect an invention, some basic requirements of patentability must be met. These requirements reflect the laws of industrial property: novelty, inventive activity, and industrial application (Blackman 2004).

Nanomaterials are materials with one or more components that have at least one dimension in the range of 1–100 nm and include nanoparticles, nanofibres and nanotubes, composite materials and nano-structured surfaces (Braun et al. 1997; Schulte 2005; Buzea et al. 2007). These include nanoparticles as a subset of nanomaterials, currently defined by consensus as single particles with a diameter <100 nm. Agglomerates of nanoparticles can be larger than 100 nm in diameter but will be included in the discussion since they may break down when subjected to weak mechanical forces or in solvents. Nanofibres are a subclass of nanoparticles (include nanotubes) which have two dimensions <100 nm but the third (axial) dimension can be much larger (Borm et al. 2006).

The prospective studies use various methodologies to provide support for the strategic planning processes of organizations and business companies as well as public and sectoral policies. A prospective approach has also been used for setting investment priorities and agendas in such areas as education, health and social activities (Santo et al. 2006; Feldman and Sanger 2007; Jin et al. 2007). The use of bibliometrics for patent analysis is arguably a valid method to use in citation analysis, allowing for the identification and description of a series of standards in the production of scientific knowledge (Daim et al. 2006). In a large study conducted by researchers of Policy Research in Engineering, Science and

Technology (PREST), an Institute of the University of Manchester, about 800 prospecting studies were analyzed worldwide, confirming that bibliometrics has been the method most used in prospective studies (Porter and Cunningham 2005; Wei et al. 2011; Antunes et al. 2012; Sant'Anna et al. 2013).

Like any method, the use of patents as indicators of innovation has limitations: innovations do not always correspond to patented inventions and not all patented inventions have economic or technological value. That is, not all products are patented and not all patents generate products. Considering, however an area of intense capital mobility like nanotechnology, patenting dynamics offers potentially valuable intelligence about emerging products (Schummer 2004; Wang et al. 2012).

The number of patents granted to an organization or applicant's country of origin reflects its technological strength and the observation of patented technologies can indicate the direction of technological development (Porter and Rafols 2009). Bibliometrics applied to patents provide quantitative research assessment exercises of technological output (Coatrieux et al. 2004; Porter and Cunningham 2005; Guan and Shi 2012).

Nanotechnology developments continue to be produced at exponential rates for a wide and diverse range of applications (Rediguieri 2009; Erdi et al. 2012). Identifying the main characteristics and prospects of nanotechnology as an emerging technology on various areas, the aim of this paper is to analyze the main trends of patenting related to nanotechnology, its development and environmental implications. It is also a goal to assist Brazilian policy-makers to adapt and modernize the regulatory framework on nanotechnology, by suggesting recommendations for governments, industry, and national organizations to create specific subsidies for the regulatory framework in the country.

Methodology

To collect data on patents in Brazil the INPI (Brazilian National Institute of Industrial Property) database for the period of patent applications filed from 1991 to 2011 was used.

Our approach to developing a nanotechnology bibliometric search involved these steps: A quantitative approach based on a bibliometric analysis of data obtained in the INPI database was employed. Data were collected within the last Electronic Journal of Industrial Property (EJIP) (INPI 2011), using 18 terms related to nanotechnology. In addition to the terms proposed by INPI, others were included, based on articles that deal with search strategies or bibliometrics analyses on nanotechnology (Coatrieux et al. 2004; Porter and Cunningham 2005; Daim et al. 2006; He and Loh 2010; Sant'Anna et al. 2013). The terms were truncated in order to optimize and maximize results and are as follows: Dendrimer*, Nanod*, Nanom*, Fio* Quantic*, Nanoe*, Nanonet*, Fuleren*, Nanof*, Nanop*, Grafen*, Nanog*, Nanos*, Nanoh*, Nanob*, Nanot*, Nanoc*, Nanoi*, and Ponto* Quantic*.

In order to undertake this survey, a selection was made of patent documents (patents, utility models and certificates of addition to invention), containing in their title and / or abstract, at least one of the 18 terms listed above. Utility models were also included because they are susceptible to industrial application, and also certificates of addition, which detail any improvements or developments to patented inventions. In all, a total of 1,343 patent applications were selected.

As for data regarding to the legal process, the following fields were collected: (1) filing date, (2) application title given by the inventor to his invention, (3) name of the depository—patent holder or organization, (4) notification—stage of the patenting process,

(5) EJIP issue which published the notification, (6) date of EJIP publication, (7) applicant's country of origin, and (8) International Patent Classification (IPC) main application.

Aiming to classify patents according to their nanotechnology application in different sectors, those with IPC main sectors related to electronics, optical-electronic, medicine and biotechnology, measurement and manufacturing, environment and energy, and nanomaterials, were selected, following the methodology proposed in a study published by the Organization for Economic Co-operation and Development (OECD) (Igami and Okazaki 2007) and presented in Table 1. The cut-off point analysis was made based on the Pareto principle, also known as the 80–20 rule, the law of the vital few, and the principle of factor sparsity; states that, for many events, roughly 80 % of the effects come from 20 % of the causes (Pareto 1949).

The typology of each applicant was evaluated, detaching their peculiarities: (a) legal entity non-resident; (b) legal entity resident; (c) individual non-resident; (d) individual resident; (e) scientific and technological institution, non-resident; and (f) scientific and technologic institution resident.

To identify and analyze the focus patents, there was a need to obtain more quantitative data on them, since the INPI database only provides the title and a brief summary. It was decided to supplement the information through Derwent Innovations Index® database, Thomson Reuters.

The Derwent Innovations Index®, available through the ISI Web of Knowledge interface, is a Web-accessible product that merges the Derwent World Patents Index with the Derwent Patents Citation Index. It provides access to more than 14,800,000 patents with links to cited and citing patents, cited articles, and full-text patent data sources. This resource gives users a comprehensive and international overview of inventions in three categories: chemical, electrical and electronic, and engineering. On this basis the titles and summaries are written by experts who make the text more concise, accurate and relevant information respecting declared in claims. The summary details how innovation can understand, use and benefit, description, technological focus, among others. To complement information, the patents identified at INPI database were analysed on the Derwent database, so that the number process of these patents could be converted to adequate format of research.

For patent-mining the automated data mining tool, VantagePoint 7.1 (Search Technology, Inc) was used. This software is a powerful text-mining tool for acquiring knowledge in the search results from patent and literature databases.

Results

After patent searches were performed with all the terms identified in the two databases selected, 1,343 patent applications were found. Figure 1 shows the historical evolution (1991–2011) of these applications in Brazil. It is worth noting the comparison that is presented on the participation of nanomaterials in quantitative nanotechnology products, for its importance in economic sectors. It is noted that the first patent application in nanotechnology is shown within the studied period. It is also noted that the peak in the number of patent applications occurs from 2004 to 2010, as a result of various funding initiatives directed at nanotechnology research, mainly by the Funding Authority for Studies and Projects (Finep), and the National Council for Scientific and Technological Development (CNPq), starting in 2003.

Table 1 Subsectors of nanotechnology and their IPC subclasses

Field name	IPC	Definition in IPC subclasses
Electronics	H01L	Semiconductor devices; electric solid state devices not otherwise provided for
	H01J	Electric discharge tubes or discharge lamps
	G06N	Computer systems based on specific computational models
	G11	Information storage
Optoelectronics	G02	Optics
	H01S	Devices using stimulated emission
Medicine and biotechnology	A61	Medical or veterinary science; hygiene
	C12	Biochemistry; beer; spirits; wine; vinegar; microbiology; enzymology; mutation or genetic engineering
Measurements and manufacturing	G01	Measuring; testing
	B01	Physical or chemical processes or apparatus in general
	B21	Mechanical metal working without essentially removing material; punching metal
	B23	Machine tools; metal working not otherwise provided for
	B32B	Layered products, i.e. products built-up of strata of flat or non-flat, e.g. cellular or honeycomb form
Environment and energy	C02F	Treatment of water; waste water sewage or sludge
	H01M	Processes or means, e.g. batteries, for the direct conversion of chemical energy into
Nano materials	B01J	Chemical or physical processes, e.g. catalysis colloid chemistry; their relevant apparatus
	B81B	Micro-structural, devices or systems, e.g. micro-mechanical devices
	B82B	Nano-structures; manufacture or treatment thereof
	C01B	Non-metallic elements; compounds thereof
	C01G	Compounds containing metals not covered by subclasses C01D or C01F
	C03B	Manufacture, shaping or supplementary processes
	C03C	Chemical composition of glasses, glazes or vitreous enamels, surface treatment of glass; surface treatment of fibres or filaments from glass minerals or slags; joining glass to glass or other materials
	C04	Cements; concrete; artificial stone; ceramics; refractories
	C07	Organic chemistry
	C08	Organic macromolecular compounds; their preparation or chemical working-up; compositions based thereon
	C09	Dyes; paints; polishes natural resins; adhesives, compositions not otherwise provided for applications
	C22	Metallurgy; ferrous or non-ferrous alloys; treatment of alloys or non-ferrous metals
	C23C	Coating metallic material coating material with metallic material; chemical surface
	C30	Crystal growth

Source Igami and Okazaki (2007) (study published by the OECD)

With the aim of classifying nanotechnology patenting, a selection was made based on the IPCs of each specific application sectors and grouped according to the methodology previously outlined. This resulted in six groups: nanomaterial (542 patents), medicine and

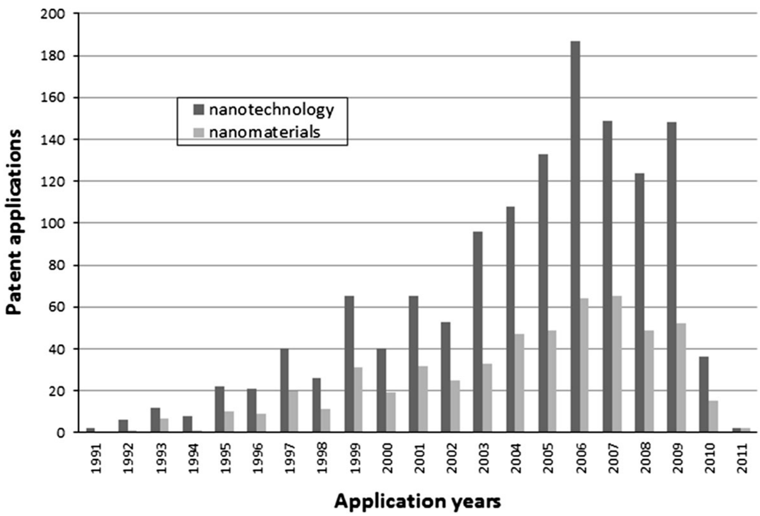

Fig. 1 Historical evolution of patent applications in Brazil (1991–2011)

biotechnology (364 patents), measurement and manufacturing (135 patents), electronic (35 patents), environment and energy (30 patents), and optical-electronic (13 patents). Figure 2 shows the percentage of the distributions, denoting nanomaterial sectors with greater expressiveness, 40 %.

Table 2 shows the nationality of applicant. Of these 542 applications for Nanomaterial patents filled in Brazil, about 27.1 % of applicants are Brazilians.

In 147 Brazilian patents, 81 different applicants were identified, including individuals and corporations, indicating a wide dispersion of applicants. Among these, the highest frequency was the State University of Campinas which filed 16 patents, and from these, two patents were in partnership with Orbys Development Materials Technology Ltd., involving latex-based nanocomposites, one patent was in partnership with Rhodia-Ster Fibers and Resins Ltd., involving clays, and one patent was in partnership with Contech Biodegradable Products Ltd., involving porous materials. In sequence there appears the University of São Paulo with 12 patents, of which eight are products of partnerships: three patents in partnership with the Foundation for Research Support of São Paulo, involving electropolymerization, nanotubes and nanoparticles, one patent in partnership with the National Commission of Nuclear Energy; one patent in partnership with the University of Brasilia Foundation; one patent in partnership with the Technological Research Institute of São Paulo; one patent in partnership with the State University Midwest, and one patent in partnership with the Tavex Brazil Corporation. Patents from the University of São Paulo generally involve manufacture and nanostructure processing, concentrated in IPC B82B.

In 395 patent applications from foreign sources, 257 different applicants were identified, including both individuals and corporations. The corporate applicants of higher frequency are shown in Table 3.

Basf SE leads the patenting in nanomaterials among foreign companies in Brazil. The majority of its patent documents are in the IPC C08 classification, macromolecular organic compounds. In general, it can be said that this company's patents involve methods and compositions for adhesives, paints, coatings and other chemical applications using

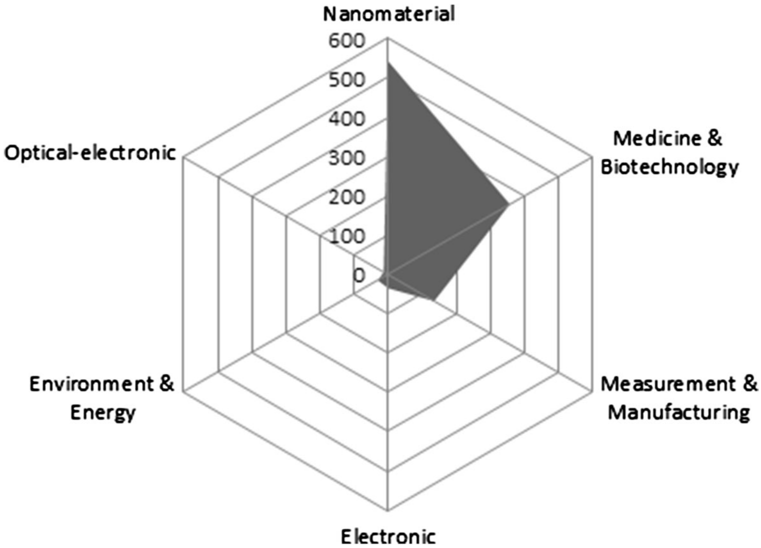

Fig. 2 Distribution of nano patents percentage by sectors

nanocomposites. In second place is the Rohm and Haas Company, whose patent documents are also concentrated in IPC C08, involving polymeric nanoparticles with wide applications in different coatings. The patents of Ohio PPG Industries Inc. are focused in the area of glass and coatings. Dow Global Technologies Inc. has its patents related to polymer nanocomposites. The Goodyear Tire & Rubber Company focuses on rubber and elastomer nanocomposites. 3M Innovative Properties Company has their patent documents distributed among different nanomaterial compositions and processes.

Discussion

Advances in the development of nanotechnology have led to several initiatives aimed at standardization of these activities (Marchant and Sylvester 2006; Mcintyre 2012). The risks to human health, exposure routes for nanomaterials in the human body and occupational safety are recent issues that need further development (Mccomas and Besley 2011). Being an innovative process, there is a substantial increase in nanopatent applications worldwide. Focusing on patents is a way of monitoring the production of products and services.

In the world scenario several initiatives for the regulation of nanotechnology are being undertaken. The American Congress, in December 2003, declared that the National Initiative for Nanotechnology should not be limited to technical issues, but also requires engagement with related ethical, legal, social, health, environmental, safety issues involving the work force and education (Cameron 2006).

In 2005, the First International Meeting on Standardization of Nanotechnology, organized by the British Standards Institution took place, which was attended by delegations from twenty two countries, with the aim of ensuring that UK would have a leading role in the creation of standards that guaranteed to the country the growth of this emerging

Table 2 Nationality and Quantitative applications for Nanomaterial patents (1991–2011)

Number of applications	Patent applications by country of origin
167	USA
147	Brazil
55	Germany
46	France
23	Netherlands
13	UK
12	Italy
11	Belgium
9	Switzerland
8	Australia
8	Canada
7	Japan
7	Norway
5	South Korea
4	Spain
4	Finland
4	Portugal
3	Austria
2	Chile
2	India
2	Israel
2	Mexico
1	South Africa
1	China
1	Cyprus
1	Cuba
1	Denmark
1	Poland
1	Sweden

Table 3 Major applicant in nanomaterials from foreign countries (1991–2011)

Quantity of patent applications	Corporate depositor (country)
23	Basf SE (Germany)
19	Rohm and Haas Company (USA)
13	Ohio PPG Industries Inc. (USA)
11	Dow Global Technologies Inc. (USA)
8	The Goodyear Tire & Rubber Company (USA)
7	3M Innovative Properties Company (USA)

industry. Other countries such as Japan and Germany, have also held several discussions concerning specific measures needed in national laws (Shindo 2005; Blind and Gauch 2009).

Focusing on some initiatives in Brazil, this theme has been discussed by the Brazilian Research Network in Nanotechnology, Society and the Environment, which, since 2004, has held seminars every 2 years. These contribute to raise questions and promote reflection on the rules and regulations governing products and processes regulation involving nanotechnology. This movement follows the logic that occurred in other technologies such as the genome or genetically modified organisms, which have developed research programs called ELSI (Ethical, Legal, and Societal Implications).

The Brazilian Federal Government launched the National Nanotechnology Program, which united the prospects related to the Nanoscience Program and the Nanotechnology Program of the 2004–2007 Pluriannual Plan, with guiding actions to influence the Brazilian scientific and technological scenarios (Brasil 2005). The Brazilian Government is working towards a New National Policy for Science, Technology and Innovation in Health to improve coordination between the principal funding agencies for health research, namely the Ministry of Science, Technology and Innovation, and the Ministry of Health. The purpose of this large-scale planning is based on consider how to strengthen the link between scientific research and activities to benefit public health.

The seminar on Nanotechnology, Society and Environment held in 2006, in the session entitled “Nanotechnology, Innovation and Regulation”, talked about the need to define public policies capable of driving the country in the direction it wants to follow in relation to nanotechnology and the risks it entails. And, in 2008, Brazil acknowledged the importance of the topic and launched the Productive Development Policy, with its inclusion among the 22 sectors of the economy, where the goal is to reduce dependence on foreign entities..

The Brazilian Agency for Industrial Development (ABDI) is an autonomous agency, created by the terms of Law No. 11080, December 30, 2004 and the Decree No. 5352, January 24, 2005, which operates in the implementation, coordination and monitoring of the Brazilian industrial policy. It elaborated the Prospective Study on Nanotechnology 2008–2025, aimed at providing the basis for structuring a schedule with guidelines and actions for the short, medium and long terms, linked to the development of nanotechnology applications identified as the most promising and strategic for Brazil.

Nanotechnology, as an important information base, has inspired activity in Brazil in this field. It should be noted that, in April 2007, the ISO Focus + , published by the International Organization for Standardization (ISO) dedicated to nanotechnology, directed efforts to implement and to structure the regulatory framework for this area. In June 2005, the ISO formed a new Technical Committee to help focus the world’s attention on standards that would support the growth of nano-related industries. The scope of that committee, ISO/TC 229—Nanotechnologies, included standardization in terminology areas and nomenclature; measurement and instrumentation; material specifications; and health, safety and environment. The standards that were created by this committee can be utilized by national organizations to support regulatory activity within nanotechnology development.

With regard to Brazil, there is no consensus on nanotechnology regulation. Likewise, there are signs that the regulation should be focused on the adequacy of existing standards for nano-scale products (Paschoalino et al. 2010). Beyond that, there are several proposals being designed accordingly, sometimes enacting, and sometimes adapting regulations, aiming at optimization of the regulatory framework in the country. Thus, in order to empower implementation of innovation policy, the Ministry of Science, Technology and Innovation devised a structure to provide new funding. Funds for scientific and technological development are being created and implemented with the aim of rebuilding the capacity to grant incentives for financing research and development and innovation. Such funds have brought to the fore the establishment of coordinating committees bringing together representatives of government, the productive sector and academia and are responsible for setting up guidelines, and selecting and monitoring projects to be financed. In addition to that, the research projects to be financed have to include both enterprises and scientific and technological institutions.

It is worth noting that the various existing laws in the country may even come to support the use of nanotechnology, based on the preambles contained in Brazilian Industrial Property Law (Law No. 9.279, 14 May 1996). The TRIPs (Trade-Related Aspects of Intellectual Property Rights) agreement was undoubtedly a key factor for legislative update, as was international pressure to conform to the rules of the World Trade Organization. In practical terms, the Industrial Property Law allowed an increase of patentable materials, providing protection in all fields of technology. However, the granting of patents, especially those related to processes for pharmaceutical products, is dependent on the prior consent of The National Health Surveillance Agency (ANVISA).

Conclusion

The deepening of the present study aims to support the scientific debate on issues for the development and application of such products, generating benefits for the future formulation of public policies in order to adapt and modernize the regulatory framework on hazards involving nanomaterials, such as the strategic policies of science, technology and innovation, as well as the public health in Brazil.

Advances in the development of nanotechnology have led to several initiatives to standardize these activities. The new frontiers of knowledge on nanomaterials are providing development such as technological innovation, and thus linking this regulation with new technologies without losing sight of the current stage of scientific development of the country. The risks to human health, exposure routes of nanomaterials on the human body and safety are issues that need further research.

Undoubtedly there are incipient data based on epidemiological studies on the potential risks posed by nanoproducts. The population could be exposed to nanomaterials directly or indirectly, since after wear or degradation of nanomaterials, in pharmaceuticals, cosmetics, paints, textiles, electronics and fuel, nanoparticles may be released. Potential routes of exposure are inhalation, skin absorption (especially with regard to cosmetics), ingestion and injection.

Understanding that nanotechnology is pervasive, that is, able to operate in different sectors of the economy, it is clear that to regulate the use and commercialization of nanotechnology in Brazil, it is necessary that the legislative framework be adequate and modernized or specific to the issues, as other pioneer countries are doing.

Given this technological convergence of nanotechnology, it is believed that there is still no generic regulatory mechanism that can realize the dreams of researchers. The risks that come with advancing nanotechnology research only tend to increase, while, on the other hand, there is a lack of discussion about the scope of its consequences. For this reason, there is a current need for prudent measures based on the precautionary principle, in order not to interrupt or stop technological development, but to ensure and preserve basic rights, such as respect for life and the right to an ecologically balanced environment.

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