

Relating patenting and peer-review publications: an extended perspective on the vascular health and risk management literature

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Purpose: This investigation identifies patent applications published under the international Patent Convention Treaty between July 2010 and January 2011 in three significant fields of vascular risk management (arterial hypertension, atherosclerosis, and aneurysms) and investigates whether the inventors have also published peer reviewed papers directly describing their claimed invention.

Results: Out of only 48 patent documents that specifically addressed at least one of the above-mentioned fields, 15 had immediate companion papers of which 13 were published earlier than the corresponding patent applications; the majority of these papers were published by noncorporate patentees. Although the majority of patent applications (30 documents) had at least one corporate assignee, 18 came from academic environments. As expected, medical devices dominated in the aneurysm segment while pharmacology dominated hypertension and atherosclerosis.

Conclusion: Although information related to hypertension, atherosclerosis, or aneurysms that was claimed in international patent applications reached the public quicker through the corresponding peer review document if one was published, more than two-thirds of the patent applications had no such companion paper in a scientific journal. The patent literature, which is freely available online as full text, offers information to scientists and developers in the fields of vascular risk management that is not available from the peer reviewed literature.

Keywords: hypertension, atherosclerosis, aneurysm, patents as topic, publishing

Introduction

There is no shortage of published information in the field of vascular risk management. In mid-February 2011, a PubMed search with the stringent term combination “blood vessels” [MeSH Terms] AND “risk management” [MeSH Terms] returned 3,603 hits, of which 535 had been published in 2010 or later; 600 were freely available as full text. These figures probably capture the majority of the PubMed-listed papers which have some degree of focus on vascular risk management, although an exact assessment of indexing precision is impossible because there is no single “correct” way to index a biomedical paper. (The current indexing practice in PubMed is a combination of MeSH terms provided by authors and those assigned by experienced human indexers at the National Library of Medicine, with algorithmic assistance).

However, neither the scientific journals that are included in the PubMed database nor the peer reviewed academic literature as a whole constitute a full representation of the public biomedical knowledge. A vast amount of information is published in the form of patent applications which are not peer reviewed according to scientific

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criteria, but instead by a patent examiner. Moreover, the motivations for filing a patent application and for submitting a manuscript for publication in a scientific journal differ substantially: while a paper is intended to offer data that allow new insights, a patent application is filed based on the expectation that the invention claimed therein could have practical applications within the next few years. This endows the “patent information universe” with an application-driven perspective instead of a science-oriented one, and therefore the patent record can potentially offer a very different perspective on new developments.

The concepts of “novelty”, “obviousness”, and “inventive content” are of central importance in patenting but their meaning in the framework of intellectual property is quite different from the way academic research commonly interprets them; rather, these terms are applied in a strictly defined legalistic fashion. For example, combining a particular antihypertonic drug and a particular diuretic can have “novelty”, even though members of the antihypertonic and diuretic drug classes have been combined for decades to treat hypertonia synergistically. The only proviso is that the particular combination being claimed as new has not been explicitly described prior to the filing date of the patent application (the priority date) in a fashion that makes it – in principle – accessible to the public, even if it has not been published in the academic sense. Even if the particular combination of drug species has been described earlier as being effective in treating hypertonia, a ratio between the compounds (or a dose) that is outside the previously described range can suffice for novelty. To carry the example further, “obviousness” is not defined by what a research cardiologist would view, but rather by what the “average knowledgeable person in the general field” (in this case, a pharmacologist with no research and development ambitions) could deduce by combining facts reported in the public “prior art” – without doing any experimental work.

On the other hand, any publicly available reference that predates the priority date of the patent application and describes the exact content of the claimed invention will negate novelty (and might create obviousness even if the description is not exact), and for this it does not have to appear in the academic or patent literature. For anybody who wants to have his or her work represented in both the academic and the intellectual property universe, it is essential to file the patent application before submitting the manuscript to a journal or making a congress presentation.

Using a comprehensive database of ophthalmological patent applications we have already reported case studies that demonstrate how patents can either anticipate the

appearance of information in the peer review literature, or else can contain information that is never published in scientific journals.¹ However, no systematic investigation had been undertaken at this time concerning whether inventions claimed in patent applications are also reported in the peer review literature. Such analyses of paired papers and patents in medical sciences are extremely scarce, and have mainly focused on the suspected restrictive influence of patenting on the dissemination of scientific information.²⁻⁴ The present paper reports a pilot study that analyzes the most recent international patent application record in three major fields of relevance for vascular risk management (arterial hypertension, atherosclerosis, and aneurysms), and relates this information to the peer review record as represented in the United States (US) National Library of Medicine’s PubMed literature database.

Materials and methods

The World Intellectual Property Organization’s Patent-Scope database⁵ was searched for the keyword terms “hypertension”, “atherosclerosis”, and “aneurysm” using date delimiters July 1, 2010 and January 31, 2011 and ignoring patent classification codes. Retrieved intellectual property documents were examined for their actual specific content concerning the above subjects; documents that named these conditions without specifically dealing with the subject matter were discarded. For example, documents that actually claimed drugs for treating diabetes and addressed hypertension and/or atherosclerosis only as diabetic complications were omitted from consideration, as were documents claiming drugs for dyslipidemia that named atherosclerosis. Also, documents that referred only to new crystal forms or other minor physical modifications to known active agents were omitted, while documents claiming innovative new formulations were included.

For each identified patent document, PubMed was searched for papers published from the patent document priority date onward and naming at least one of the inventors as an author. If the patent content suggested MeSH terms or free-text keywords, an additional search was conducted based on these terms. PubMed hits were then examined based on their abstracts (and full texts if available) to identify “companion papers” to the respective patent documents. A peer review paper was considered a companion paper if it had at least one inventor as an author, and captured the scientific and/or technical essence of the patent document. (Note that a peer review paper with a content largely identical to that of a patent that were published prior to the patent’s

filing date would invalidate the patent, therefore extending the PubMed search to earlier periods was not considered meaningful).

Results

Tables 1–3 present the key data of the identified international patent applications, and relate them to their companion peer review papers.

Hypertension: Of the 26 documents identified, 19 came from 16 different companies while seven had been filed by universities, hospitals, or foundations. The great majority (21 documents) concerned themselves with pharmaceuticals, while the remaining five dealt with biomarkers, surgical methods, or model algorithms. Only seven patent applications had direct peer review equivalents.

Atherosclerosis: Only eight patent applications were identified, with an even distribution between public and private assignees; six concerned pharmacological treatments; four had companion papers.

Aneurysm: Fourteen international patent documents, also with assignees evenly distributed between the corporate and noncorporate domains, were published during the period covered by our investigation; four had peer review equivalents. With the exception of three submissions claiming diagnostics, all were concerned with repair and stabilization devices. Five documents focused on cerebral aneurysms.

In total, 15 out of 48 patent applications had companion papers and 30 had at least one corporate assignee. Of the 15 patent-paper pairs, nine were published by academic or foundation inventors while six came from corporate inventors.

A closer look at the publication dates revealed that in all but two of those cases where a companion peer review paper had been published, it had appeared in print earlier than the corresponding patent document. This became even more pronounced if electronic publications ahead of print were included in the consideration (data not shown). Therefore a strong dichotomy resulted: while for the majority of patents the information was not available in peer review format at all, those cases where the information was also published in peer review journals tended to reach the public earlier in their peer reviewed versions. In several cases the paper preceded the corresponding patent by a year or more.

Discussion

Patent documents are very different from scientific journal papers in terms of intent, semantics, pre-publication critique, and publishing policy. The primary purpose

of submitting a manuscript to an academic journal is to communicate new scientific data and information concisely to a specialized audience of peers. At least two of these peers will anonymously review the manuscript and decide its fate according to the commonly accepted criteria of the scientific community.

In contrast, a patent is filed with the perspective of securing exclusivity of use with respect to future commercial applications and to strategically preserve the inventors' and assignees' competitive edge. The requirement for legally explicit statements frequently leads to the use of language that is considered repetitive, redundant, or outright trivial by the average scientist working in the respective field. Review is by a single, personally identified examiner who is not necessarily an expert in the particular field, and who conducts the review according to legally defined criteria without attempting an assessment of feasibility (such as, for example, whether a particular vascular repair device would make sense in clinical practice). Regardless of the result of this examination, every patent document is published within about 18 months of its filing date unless the submission is retracted.

Virtually every single one of these features of a patent document runs counter to what academic researchers in the life sciences or in medicine expect from a published paper. As a result, life scientists frequently ignore patents while researchers working in technical, engineering, or software development fields traditionally value them highly.

This analysis of patenting versus peer-review publishing in three major fields of vascular risk management shows that disregarding published patent documents as a source of novel information can severely limit researchers' knowledge: 33 out of 48 documents had no direct equivalent in the peer review literature. Interestingly, this lack of matches was most pronounced in the field of hypertension which, as we had expected, had the most patent documents. However, there were a surprisingly low number of relevant patent documents identified overall so that conducting an actual comparative analysis for each field would not have been meaningful.

The analysis shows a dominance of corporate over academic and nonprofit organization assignees, however, the dominance is a relatively slight one (63%). The present investigation did not involve direct comparison with equivalent earlier periods, but analyses that are available for US patents show that allowing US universities to claim title to inventions that had been made with federal funding have dramatically increased academic representation in

Table 1 International patent applications concerning arterial hypertension, July 2010 to January 2011

Patent number	Assignee and country	Subject	Published	Companion paper
WO/2011/008001	CJ Cheiljedang (KR)	Antihypertensive composition containing a ginsenosides enriched fraction of ginseng extract	January 20, 2011	None
WO/2011/004040 WO/2011/004038	Universidad de Sevilla (ES)	Captopril or L-carnitine for controlling the cardiac inflammatory process that accompanies arterial hypertension	January 13, 2011	<i>J Inflamm (Lond)</i> . 2010;7:21 and <i>J Physiol Biochem</i> . 2010;66(2):127–136
WO/2010/150921	Teijin Pharma (JP)	A 2-phenylthiazole agent for hypertension or high-normal blood pressure	December 29, 2010	None
WO/2010/148411	Entelos (US)	Novel computer models of hypertension comprising a renin-angiotensin-aldosterone system (RAAS) pathway module, a renal function module, and a blood pressure regulation module	December 23, 2010	None
WO/2010/146551	Ranbaxy Laboratories (IN)	Orally disintegrating compositions comprising angiotensin II receptor antagonists for hypertensive crisis	December 23, 2010	None
WO/2010/143059	Generex Pharmaceuticals (CA)	<i>Geum japonicum</i> plant extracts for preventing or treating hypertension	December 16, 2010	None
WO/2010/142794	Bios International (IT)	Non-enzymatic in vitro method for detecting gp91 ^{phox} as a marker of oxidative stress, including hypertension, atherosclerosis, cardiac hypertrophy, and stroke	December 16, 2010	None
WO/2010/137336	Kowa (JP)	Alpha-phenoxybenzeneacetic acid derivatives that are angiotensin II receptor antagonists and PPARgamma agonists, for hypertension and metabolic syndrome	December 2, 2010	None
WO/2010/129379	Merck Sharpe and Dohme (US)	Inhibitors of the Renal Outer Medullary Potassium (ROMK) channel (Kir1.1) with diuretic and natriuretic action for hypertension and chronic and acute heart failure	November 11, 2010	None
WO/2010/127096	Midwestern University (US)	Cenchaquin and related adrenergic agents for treating hypertension, pain, and resuscitative hemorrhagic shock	November 4, 2010	None
WO/2010/124201	Invasc Therapeutics (US)	Methylenedioxyphenyl ferulate, ferulylproline, and derivatives thereof as myeloperoxidase inhibitors and vasodilators for cardiovascular diseases	October 28, 2010	None
WO/2010/124120	Mercator Medsystems (US)	Minimally invasive surgery with local application of guanethidine into the adventitia to reduce the activity of the sympathetic nerves surrounding the renal artery, for the treatment of renal and arterial hypertension	October 28, 2010	None
WO/2010/119700	Kowa (JP)	Dual angiotensin II receptor antagonist and PPARgamma agonist, for hypertension and metabolic syndrome	October 21, 2010	None
WO/2010/116282	Pfizer (US)	4,5-Dihydro-1H-pyrazole mineralocorticoid receptor antagonists for diabetic nephropathy and hypertension	October 14, 2010	<i>J Med Chem</i> . 2010;53(16):5979–6002

(Continued)

Table 1 (Continued)

Patent number	Assignee and country	Subject	Published	Companion paper
WO/2010/104721	Eli Lilly (US)	5-((E)-(3-fluorodibenzo[b,e]oxepin-11(6H)-ylidene)methyl)-1-((7R,8aR)-hexahydro-1 H-pyrrolo [2,1-c][1,4]oxazin-7-yl)-1 H-benzo[d]imidazol-2(3H)-one, a mineralocorticoid receptor antagonist for kidney disease, hypertension, and heart failure	September 16, 2010	None
WO/2010/104646	Scott and White Memorial Hospital (US)	Simultaneous measurement of marinobufagenin and angiotensinogen in urine to differentiate volume extension and vasoconstrictive forms of hypertension	September 16, 2010	None
WO/2010/099054	Merck Sharpe and Dohme (US)	Soluble guanylate cyclase activators for endothelial dysfunction, atherosclerosis hypertension, and heart disease	September 2, 2010	None
WO/2010/096677	Invasc Therapeutics (US)	Dinitroso-derivatives of dihydroliipoic acid for hypertension, myocardial infarction, stroke, atherosclerosis ect.	August 26, 2010	None
WO/2010/095462	Kowa (JP)	3-(5-Akoxypyrimidine-2-yl) pyrimidine-4(3H)-one dual angiotensin II receptor antagonist and PPARgamma agonist, for hypertension and metabolic syndrome	August 26, 2010	None
WO/2010/092811	Nihon University (JP)	Biphenylcarboxamide compound for hypertension	August 19, 2010	None
WO/2010/088279	Cardiomems (US)	Wearable wireless blood pressure monitoring system with implanted sensor	August 5, 2010	None
WO/2010/084231	Fundació Institut de Recerca de L'Hospital Universitari Vall d'Hebron (ES)	Kidney androgen-regulated protein (KAP) gene expression in renal tissue, for models to evaluate antihypertensive compounds	July 29, 2010	<i>Circulation.</i> 2009;119(14):1908–1917
WO/2010/082367	Kikkoman (JP)	Orally bioavailable angiotensin-converting enzyme (ACE)-inhibiting di- and tripeptides	July 22, 2010	<i>J Agric Food Chem.</i> 2010;58(2):821–827
WO/2010/080183	University of Columbia (US)	Vasodilatory and anti-inflammatory soluble epoxide hydrolase inhibitors to treat hypertension	July 15, 2010	<i>Bioorg Med Chem Lett.</i> 2009;19(8):2354–2359
WO/2010/078624	Vegenics (AU)	Vascular endothelial growth factor (VEGF) C and D products for hypertension	July 15, 2010	<i>Nat Med.</i> 2009;15(5):545–552

patenting during the following two decades.⁶ An analysis of the patenting and publishing data of 395 academic inventors from five major universities in Taiwan from 2002 to 2006 suggested that patenting might increase the number and quality of papers published by these inventors.⁷

Although the absolute numbers are too low for actual statistics, the available data suggest that corporate inventors are less likely to publish their patented findings in scientific journals than nonprofit inventors. This was expected, since peer-review publishing is firmly rooted in academic culture while the standing of corporate scientists in the life sciences,

or their companies, is not usually measured by such criteria. Patents are deemed far more important in this environment. If a 1987 analysis of 17 US pharmaceutical companies has demonstrated their patent data to represent an excellent indicator of overall corporate technological strength,⁸ there is little reason to assume that this situation has changed fundamentally. In addition, most patents that claim incremental improvements over the prior art (eg, a new orally disintegrating tablet formulation for a particular compound, or a variation in the design of a vascular repair device) would not meet the criteria of “novelty” and “non-obviousness”

Table 2 International patent applications concerning atherosclerosis, July 2010 to January 2011 (excluding antihyperlipidemic, antidiabetic, and nonspecific anti-inflammatory drugs)

Patent number	Assignee and country	Subject	Published	Companion paper
WO/2011/005608	Merck Sharpe and Dohme (US)	Cyclohexyl sulfonamide platelet-activating factor (PAF) receptor antagonists	January 13, 2011	None
WO/2010/133662	INSERM (FR)	Interleukin-17 polypeptides for the prevention and treatment of atherosclerosis	November 25, 2010	<i>Curr Opin Lipidol.</i> 2010;21(5): 404–408
WO/2010/126967	Boehringer Ingelheim (DE); New York University (US)	Ex-vivo treatment of blood with protein kinase C-theta inhibitors for immunological diseases and atherosclerosis	November 4, 2010	<i>Science.</i> 2010;328(5976): 372–376
WO/2010/108419	Chinese Academy of Medical Sciences (CN)	PON gene cluster to promote stability of atherosclerotic plaques	September 30, 2010	<i>Circ Res.</i> 2009;104(10): 1160–1168
WO/2010/105285	Heart Research Institute (AU)	Testing for atherosclerosis or a predisposition thereto, based on monocyte-derived endothelial cells	September 23, 2010	None
WO/2010/088455	General Hospital Corp.	Cromolyn analogs to image and treat atherosclerotic plaques	August 5, 2010	None
WO/2010/079161	INSERM (FR)	B cell depleting agent for the prevention or treatment of atherosclerosis	July 15, 2010	<i>J Exp Med.</i> 2010;207(8): 1579–1578
WO/2010/077624	Merck Sharpe and Dohme (US)	Biaryl carboxamide PAF receptor antagonists	July 8, 2010	None

that are commonly applied in academic peer review, even if the claimed improvements might be immediately applicable and useful. In this context, a lack of companion peer review papers does not indicate poor relevance of a patent.

A very limited number of investigations have been published that discuss selected aspects of patenting in the context of the vascular risk factors that are the subject of this investigation.^{9–11} While these are important reviews that illustrate certain aspects, no analysis had been previously undertaken to relate such patenting activity with conjoined peer-review publishing.

This pilot study obviously has several limitations. First, since the latest patents included in this analysis were published only three weeks prior to the time of writing, more delayed peer review companion papers might be published as time progresses. However, the two post-patent peer review papers that this analysis did reveal appeared within a few weeks of the corresponding patent. Therefore it seems unlikely that many more true companion papers will be published for the patents listed in Tables 1–3. The delays involved in PubMed indexing of some peer review journals, which can amount to several months, constitute a potentially more severe limitation of this analysis, which covers the most recent 7 months of patenting related to innovation in vascular risk management. Studies that extend over longer periods of patenting and publishing, or compare several periods, could eventually provide more insight.

The data that are available now allow the conclusion that international patent applications can offer valuable insights into new developments concerning vascular risk management which are not made available in academic peer-review publishing, at least not without a delay of many months which our limited study would not have consistently detected. This implies that systematic monitoring of the patent literature can potentially add a substantial amount of cutting edge information.

However, the obvious difficulty of the scientist having to negotiate the legalistic style and repetitive nature of patent jargon remains, as does the difficulty to identify relevant patents. While it has been argued that patent searching must become part of life science students' information literacy instruction,¹² a more pragmatic and encompassing approach could be algorithmically mapping patents to MeSH codes,¹³ which would allow integrated searches that cover both PubMed and open access patent databases. Although algorithmic parsing of typical "patent jargon" into semantics that are familiar to research scientists is only a dimly perceived possibility at this time,¹⁴ text analysis has been able for some years to effectively identify innovative patents and provide ranking and mapping.¹⁵ For specialized applications such as the vascular risk management literature, expert systems might provide broadly deployable semi-automated solutions within the next few years.

Table 3 International patent applications concerning aneurysms, July 2010 to January 2011

Patent number	Assignee and country	Subject	Published	Companion paper
WO/2011/008906	Mayo Foundation (US)	Automatic detection of cerebral aneurysms by assigning points of interest to raw image data files	January 20, 2011	<i>J Digit Imaging.</i> 2011;24(1): 86–95
WO/2011/007352	Yissum R&D (Univ. of Jerusalem) (IL)	New endovascular aortic repair technique using a flexible endoprosthesis which stiffens at the implantation site	January 20, 2011	None
WO/2010/145703	GraftCraft i Göteborg AB (SE)	Endovascular device for repair of a ruptured aneurysm, consisting of a balloon with a channel extending through it and a supporting blood-permeable stent which remains in situ for 1–2 days postoperatively	December 23, 2010	None
WO/2010/134914	University of Miami (US)	Spherical helix coils with shape memory to occlude cerebral aneurysms	November 25, 2010	<i>J Med Device.</i> 2009;3(4):41005*
WO/2010/129270	Shriners Hospitals for Children; Pregon Health and Science University (US)	Immunoassays to monitor disease progression in individuals with Marfan's syndrome, aortic aneurysm, or scleroderma based on the concentration of circulating elastic fiber and microfibril fragments (fibrillin and fibulin)	November 11, 2010	None
WO/2010/127381	James Cook University (AU)	Altering levels of components in the kallikrein-kinin system to assist in preventing or treating aneurysms	November 11, 2010	None
WO/2010/123911	Lake Region Medical, Inc. (US)	A tubular meshwork device with a patch to occlude the neck of the aneurysm upon insertion, with exact axial and rotational positioning through a marker	October 28, 2010	None
WO/2010/123831	Chestnut Medical Technologies, Inc. (US)	An occluding device that can be used to remodel an aneurysm within the vessel by neck reconstruction or balloon remodeling	October 28, 2010	<i>Neurosurgery.</i> 2009;64(4): 632–642
WO/2010/120926	Chestnut Medical Technologies, Inc. (US)	Occluding devices with adjustable porosity for tortuous vessels, especially of the neurovasculature, in proximity of oxygen-demanding tissues	October 21, 2010	<i>Neurosurgery.</i> 2009;64(4): 632–642
WO/2010/112838	Barking Havering and Redbridge Hospitals (UK)	Multi-balloon catheter device for occlusion of aneurysms, with some balloons serving as deflectors for an occluding agent	October 7, 2010	None
WO/2010/110819	Arista Therapeutics, Inc. (US)	Improved implantable device containing and light-emitting diode (LED) matrix to internally irradiate aneurysms	September 30, 2010	None
WO/2010/089491	A.L.N. (FR)	Intravascular device for occluding aneurysm, consisting of a longitudinal, partially planar mesh skeleton covered with a film	August 12, 2010	None
WO/2010/082026	Isis Innovation Ltd. (UK)	Stents for intracranial aneurysms, consisting of linked plates or rings arranged as a tube and deformable between an expanded state and a collapsed state	July 22, 2010	None
WO/2010/076838	Individual inventor (IT)	Catheter for a transcaval approach to an abdominal aneurysm	July 8, 2010	None

Note: *Same institution and subject, authors different from inventors.

Disclosure

The author reports no conflicts of interest in this work.

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