

An Unwise Move to Discriminate Against Pharmaceutical Patents: Responding to the UN's *Guidelines for Pharmaceutical Patent Examination*

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EXECUTIVE SUMMARY

Recently, United Nations agencies have encouraged countries to make it harder to get patents on pharmaceuticals. The primary vehicle for this policy has been the *Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective* (the “Guidelines”). The *Guidelines* advocate excluding entire categories of pharmaceutical inventions from patentability.

This new approach represents a departure from past patent policy. The patent system has long applied the same rules to everybody instead of discriminating against particular types of technologies or industries. Ordinarily, each invention is judged on its individual merits based on neutral and generally-applicable rules for patentability.

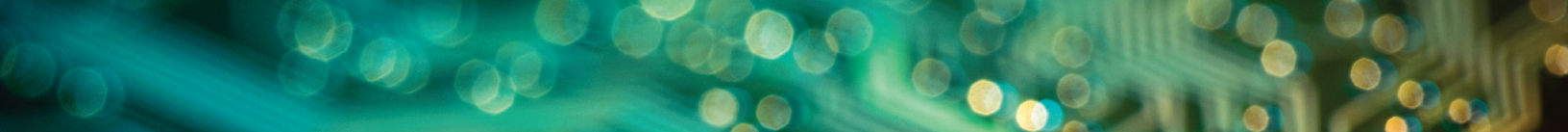
The aim of the *Guidelines* is to make medicines cheaper, which is a laudable goal, but the kind of goal that has long been kept out of patent examination for good reasons. If a government objects to the prices of a product or how a business behaves in the marketplace, it applies other laws *after* the patent is granted. But when governments interject politics and policy *before* a patent is granted, the patent system as a whole becomes unreliable and unpredictable. Businesses are reluctant to invest in unreliable property rights and in the markets that make them unreliable. They either stop investing in innovation or avoid the markets where their innovations are unprotected.

The *Guidelines* contend that many forms of pharmaceutical innovation are inherently routine and hence unpatentable by default. Consequently, they demand exceptional circumstances from pharmaceutical inventions not required in other fields. The *Guidelines* would also restrict patents on innovations that occur later during drug development, including after the initial launch of a product.

This Policy Brief provides an evidence-based review of the categories of pharmaceutical innovation addressed by the *Guidelines* and dismissed as undeserving of patents. These include “Markush claims,” selection patents, patents on different forms of the drug, prodrugs and metabolites, compositions, combinations, doses, and new medical uses. Many of these categories of inventions are rather technical, so the Policy Brief attempts to briefly illuminate what each is and why it matters to the process of discovering and bringing new drugs to patients.

Once each category is carefully explained and examined, one finds real innovations. As illustrated by the decisions surveyed in this Policy Brief, when courts delve deeply into the substance of these inventions, they are often struck by the unpredictability and difficulty inherent in pharmaceutical innovation. These innovations can provide new and beneficial ways to formulate, prepare, and deliver the drugs as well as different ways to use the drugs.

Considered in the abstract, it is easy to devalue the inventiveness of the categories of pharmaceutical innovation targeted by the *Guidelines*. However, it is hoped that this Policy Brief and the full-length version, *In Defense of Secondary Pharmaceutical Patents: A Response to the UN’s Guidelines for Pharmaceutical Patent Examination*, will provide some counterweight to balance some of the more radical, and in my view unwarranted, recommendations set forth in the Guidelines. The interested reader should consult the full-length article for an expanded explanation including examples and citations to primary sources.



An Unwise Move to Discriminate Against Pharmaceutical Patents: Responding to the UN's *Guidelines for Pharmaceutical Patent Examination*

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Introduction

For over a decade, United Nations agencies have been encouraging countries to make it harder to get patents on pharmaceuticals by adopting rules that exclude entire categories of pharmaceutical inventions from patentability. In doing so, they are discarding the normal approach to awarding patents, which examines the individual merits of each invention to ensure that it is truly new and otherwise meets the generally-applicable criteria for patentability.

The patent system has historically avoided discriminating based on technology and industry for good reasons. This new approach advocated by several U.N. agencies mistakenly blocks entire categories of pharmaceutical inventions from patentability. Proponents justify this rule change by claiming that it will promote public health by making medicines cheaper. They have found a receptive audience among national governments for that reason, but also because suppressing drug patents would reduce government budgets and boost local generic drug industries, at least in the near term. This policy is short-sighted, however, because in the medium to long run, it makes businesses less likely to do R&D, and, crucially, much slower or less likely to introduce innovative cures to countries that do not secure their rights.¹

The primary vehicle for this move to make pharmaceutical patents harder to get has been a document entitled *Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective* (the “*Guidelines*”).² The *Guidelines* have been influential in the long-running debate regarding the role of patented pharmaceuticals in public health. They were issued in 2015 by the United Nations Development Programme, and have been available in an earlier “working paper” form since 2006, jointly published by the World Health Organization, the U.N. Conference on Trade and Development (UNCTAD), and the International Centre for Trade and Sustainable Development (ICTSD).

The *Guidelines*’ stated purpose is “to incorporate public health perspectives in procedures for granting pharmaceutical patents.”³ While international law has recognized that public health considerations can and should affect the use and enforcement of pharmaceutical patents,⁴ the *Guidelines* advocate that patent offices should consider public health in determining which inventions receive a patent. Essentially, the goal is to put a thumb on the scale in favor of generic medications with less concern for the development and incremental improvement of innovative pharmaceutical products.

The stated purpose of the *Guidelines* contradicts the principle that patents should be neutral as to technologies and industries – in other words, that the same rules should apply to everybody. Generally, inventors can obtain property rights in their inventions and *then* public policy decides what, if anything, to do about them. There are many worthy public policy goals, including saving the government money on what it procures. In the short term, governments might further those goals by denying patent rights in order to reduce prices or suppress development of new technologies it deems undesirable. However, once governments interject politics and policy *before* a patent is granted, rather than after, the patent system as a whole becomes unreliable and unpredictable. Businesses are reluctant to invest in unreliable property rights and in the markets that make them unreliable. They either stop investing in innovation or avoid the markets where their innovations are unprotected.

This Policy Brief critically examines the *Guidelines* and discusses where the guidelines’ exclusive focus on generic availability through restricting patents harms its broader goal of promoting public health. While the *Guidelines* assert that they do not alter patentability requirements, their implementation would almost certainly have that effect. The *Guidelines* encourage countries to depart from traditional notions of patentability. In doing so, they exclude many valuable inventions, and thus do harm to

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the purpose of patents in encouraging pharmaceutical companies to invest in creating new cures and in making them available globally.

Understanding the Guidelines

The heart of the *Guidelines* is a category-by-category examination of various pharmaceutical patent claims: Markush claims; selection patents; polymorphs; enantiomers; salts; ethers and esters; compositions; doses; combinations; prodrugs; metabolites; and new medical uses. A small number of developing countries view patents on these innovations as impediments to access and have sought to curtail their patentability. For example, India excludes from patentability the “mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance.”⁵ Brazil and South Africa are reportedly considering legislation along similar lines.⁶ As discussed below, these views fall far outside of the mainstream understanding of the standards of patentability.

The *Guidelines* propose “recommendations” as to how patent examiners should examine these pharmaceutical patent claims in a manner that would, according to the author of the *Guidelines*, “protect public health and promote access to medicines.”⁷ The recommendations generally call for heightened patentability requirements, which would, if implemented, effectively deny patent protection to various types of pharmaceutical innovation that the patent system currently incentivizes. A “working draft” of the *Guidelines* has been widely cited and used as the basis of arguing that heightened requirements of patentability should be applied to pharmaceutical inventions.⁸ No doubt the release of the finalized *Guidelines* has served to add more fuel to the fire.

One of the primary means by which the objective of the *Guidelines* would be accomplished is through

an exceptionally rigorous application of patent law’s nonobviousness/inventive step requirement. In particular, the *Guidelines* postulate that many forms of pharmaceutical innovation are inherently routine and hence unpatentable by default. Consequently, they demand exceptional circumstances from pharmaceutical inventions not required in other fields of endeavor in order to be treated as inventive or nonobvious. But the *Guidelines*’ assumption that many types of pharmaceutical inventions are inherently obvious and undeserving of patent protection is grossly overstated, and it is based on a profoundly oversimplified view of how these inventions come about.

It is important to note at the outset that patents exist to promote research and development throughout this process. The goal is to promote the development of new and innovative pharmaceutical *products* that improve health care overall. All of the patents discussed here promote this research at different stages of the pharmaceutical life cycle. No single kind of patent will be sufficient to appropriately protect the wide variety of actual innovation that occurs in this industry.

I recently published a law review article entitled *In Defense of Secondary Pharmaceutical Patents: A Response to the UN’s Guidelines for Pharmaceutical Patent Examination*, which provides an evidence-based response to the *Guidelines* refuting, or at least qualifying, some of the significant conclusions and recommendations set forth by its author.⁹ In the present Policy Brief, I briefly summarize some of the conclusions presented in *In Defense of Secondary Pharmaceutical Patents*. The interested reader should consult the full-length article for an expanded explanation including examples and citations to primary sources.

Critiquing the Guidelines

A. Claims covering the initial development of the drug

Pharmaceutical products do not arise from “Eureka” moments in the lab. They are the product of painstaking research identifying classes of compounds that show some effect. This is followed by years of research identifying which parts of a discovered molecule contributes to the effect and refinement of the molecule in order to increase efficacy and decrease toxicity. The lucky few candidate molecules that go into human clinical trials often elicit surprising results, both good and bad.

a. Markush claims

Markush claims, which are used to protect structural variants of a chemical compound that share a common generic core, are of critical importance to pharmaceutical innovators. These claims typically are available early in the research process, when a scientist has discovered the functional part of the molecule, but has not yet optimized it for the best possible commercial product. Given the redundancy of chemical function and the astronomical number of ways in which slight variations can be introduced into a chemical compound, a patent limited to a single molecule, or a small cohort of variants actually synthesized and tested, could be easily circumvented by a competitor.¹⁰ Each circumvention would use the core functional part of the molecule, which is the inventor's actual contribution to the art, but would evade any reasonable protection by making unrelated changes.

The *Guidelines* recommend that the “coverage of [a Markush claim] should be limited to the claimed embodiments that are actually enabled by the disclosure in the specification.”¹¹ This recommendation appears on its face to be entirely consistent with the current standard in the US and abroad, pursuant to which a patent claim (Markush or otherwise) is only valid if it is “enabled” (in the legal sense) across its entire scope. However, to the extent that “actually enabled” means something narrower, such as limiting claims to molecules with experimentally verified results, this recommendation undermines the incentive to disclose what these claims secure.

Significantly, there is currently no requirement that an inventor has actually synthesized and characterized each and every molecule falling within the scope of the claim. It would be a serious mistake to require inventors to actually synthesize and test every potential permutation of a novel pharmaceutical compound, given the multiple sites for chemical substitution on a complex molecule, the multiple possible substitutions at each site, and the resulting potential for millions, if not billions, of structurally analogous molecules sharing the functionality of molecules actually synthesized and tested.

b. Selection patents

As noted above, once a functional core of a molecule has been identified as having the desired activity, research continues to find a single molecule that will have the best properties for a commercial product. The relevant properties include

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the obvious ones of efficacy and safety. Other properties also may be the necessary focus of research, such as ease of manufacturing or stability for storage. Discovering that a particular molecule exhibits advantageous properties could potentially lead to a “selection patent” if the molecule is included within the disclosure of a prior, broader class. Encouraging the discovery of these molecules in the pharmaceutical research and development should be a goal of any well-functioning patent system.

The *Guidelines* recommend that selection patents, defined as patents claiming “a subgroup of elements . . . selected from a larger group and claimed on the grounds that a new, unexpected property has been found” should not be granted, asserting that the “selection of elements included in the disclosed group lacks novelty, such as in the case of compounds disclosed in a prior generic chemical structure or included within a numerical range.”¹²

It has long been settled law in the US and Europe that disclosure of a genus of structurally related molecules does not necessarily anticipate or render obvious all of the molecules formally encompassed by the genus. This is important, because without the possibility of patent protection there would be insufficient incentive for pharmaceutical companies to discover and commercialize a chemical species having substantially improved pharmaceutical properties that other members of the genus do not possess.

c. Patents on different forms of the drug

During the research process, scientists may discover that one particular form of the drug has advantages over others. The *Guidelines* discuss several different ways that drugs can have different forms: polymorphs, enantiomers, salts, esters, and ethers. However, the relevant inquiry generally should remain the same: whether the novel form is inventive or nonobvious over the prior art. The *Guidelines* near categorical denial of patentability for inventions of this type would undermine this inquiry and discourage researchers from pursuing advancements in these areas.

Without the possibility of selection patent protection there would be insufficient incentive for pharmaceutical companies to discover and commercialize a chemical species having substantially improved pharmaceutical properties.

“Polymorphs” generally refers to the different ways that the individual molecules are ordered (or not) in a larger structure. The *Guidelines* recommend that “patents on polymorphs should be denied on the grounds of absence of a patentable invention or inventive activity.”¹³ The sole focus of patentability in the *Guidelines* is the inventiveness of the method of obtaining the polymorph. No consideration is given for the effect of the polymorph for the drug product, despite the effect being the goal of the pharmaceutical research.

The *Guidelines*’ radical recommendation entirely ignores the substantially improved characteristics sometimes found to exist in one polymorphic form of a drug relative to others, including improved bioavailability, reduced toxicity and adverse side effects, and enhanced stability. For example, in one case, a lack of bioavailability was preventing the development of a promising antibiotic into a useful product. Certain chemical changes had improved viability, but were still insufficient to get the drug to market. It was the switch from a highly ordered crystalline structure to an amorphous solid that increased bioavailability sufficient to allow for a commercially viable product, CEFTIN.¹⁴

The recommendations from the *Guidelines* also minimize the inventive activity often associated with the isolation and identification of a superior polymorph, particularly given the unpredictability of the characteristics of polymorphs and the necessity of empirical testing, often at a substantial cost and without any reasonable likelihood of success at the outset. Although acknowledging a theoretical possibility that the method of obtaining a polymorph could be patentable, the recommendations also state that “obtaining a polymorph is a routine activity in pharmaceutical production.”¹⁵ Courts in the US, Sweden, India, Colombia, and Chile, as well as the EPO Technical

Board of Appeal, have all upheld the inventiveness of patents claiming polymorphs.

“Enantiomers” are drugs with the same chemical structure that differ only by being mirror images around a single atom. A mixture of enantiomers is called a “racemic mixture,” or “racemate.” The *Guidelines* recommend that single “enantiomers should not be deemed patentable when the racemic mixture was previously disclosed.”¹⁶ Single enantiomer drugs can provide tremendous benefits to patients, including substantially improved safety and efficacy profiles, relative to the racemic version of the drug. Courts in the US, United Kingdom, Netherlands, Germany, Spain, and Canada have all issued decisions in the last decade finding patent claims reciting single enantiomers nonobvious over prior art disclosing the corresponding racemic mixture.

As with polymorphs, there are essentially two bases upon which courts have found these enantiomers inventive and patentable. Unlike with polymorphs, where the *Guidelines* at least acknowledge the possibility that the method of producing the form would be patentable, no such acknowledgement is present with regards to enantiomers.

One basis for patentability is the difficulty and predictability often associated with separating a particular enantiomer, arising from the fact that enantiomer pairs share the exact same chemical structure and chemical formula, and thus tend to have identical physical and chemical properties. There is no general methodology for separating enantiomers—each separation problem must be solved case-by-case, in an unpredictable process of trial and error experimentation. The other basis on which courts have found enantiomer claims nonobvious is based on the lack of a reasonable expectation that an isolated isomer would have had significant clinical benefit compared to the racemic mixture.

The *Guidelines* recommend that a patent claim directed towards a specific salt form of a drug, or a specific ether or ester derivative of the drug, should normally be deemed invalid for lack of inventive step. Contra polymorphs and enantiomers, for salts and derivatives, the *Guidelines* acknowledge that patentability of specific salts can be based on desirable characteristics relating to stability, bioavailability, manufacturability, and route of administration to the patient, and that ether and ester derivatives of drugs can exhibit improved safety or efficacy, but argue categorically that preparing salts and ether/ester

derivatives of drugs “is part of the common knowledge of a person skilled in the art.”¹⁷

However, the *Guidelines* incorrectly assume that “any chemistry student” can make predictions about the likely physicochemical properties of a new salt form of a drug, when in fact a pharmaceutical chemist will tell you that, as a general matter, it is impossible to accurately predict the physicochemical properties of a new salt form of a drug, or a new ester or ether derivative, regardless of how well characterized the particular counterion is when paired with other drug active ingredients.

d. Prodrugs and metabolites

In some cases, the particular form of the drug may have an important relationship to the purpose of the drug. Prodrugs are forms a drug that are by design metabolized to the active form in the body. A metabolite results when a drug is metabolized by the body into a modified form, which in some cases is the active form of the drug that, in the patent context, can be claimed as either a new product or a new use.

The *Guidelines* do not dispute the patentability of prodrugs, and explicitly acknowledge their “advantages compared to the basic drug (e.g. better stability and bioavailability, fewer side effects, better pharmacokinetic profile, increased concentration of the drug at the site of action, and longer duration of action).”¹⁸

The *Guidelines* acknowledge that “there may be advantages in administering an active metabolite compared to the parent drug,” but argue that “any advantages do not stem from inventive activity,” and that metabolites are not novel “based on the concept of inherency.” The *Guidelines* point out that in *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, the Federal Circuit held that a claim directed to an antihistamine metabolite was inherently anticipated by a prior art patent disclosing the underlying antihistamine.²⁰ However, the *Guidelines* fail to note that in *Schering*, the court emphasized that its decision “[did] not preclude patent protection for metabolites of known drugs,” and that “[w]ith proper claiming, patent protection is available for metabolites of known drugs.”²¹

The Guidelines incorrectly assume that “any chemistry student” can make predictions about the likely physicochemical properties of a new form of a drug, when in fact a pharmaceutical chemist will tell you it is generally impossible to accurately predict a new form’s physicochemical properties.

B. Claims covering ongoing development of the pharmaceutical product

Researching and discovering a molecule for a drug is only the beginning of the research path. That drug substance must then be turned into a drug product along with details of how to use it. This ongoing research requires additional innovation that, without sufficient protection, will simply not occur.

Discussions of “evergreening” often seem to suggest that when a drug company obtains a new patent directed towards an invention relating to a previously patented pharmaceutical, this subsequent patent somehow extends the duration during which generic competition is precluded. But as a general matter, that is simply not the case. While new patents might preclude some newly invented uses, they do not generally stop a generic company from selling a competing version of the original drug for the originally approved indications.

a. Compositions

Broadly speaking, a pharmaceutical composition is the detailed form of the end product. In very few cases, if any, is the final product just the purified drug molecule. Instead, the drug must be formulated with inactive ingredients, and sometimes in complicated forms that maximize the effect of the drug. The possible compositions may include the precise manufacturing of the tablet or the inactive ingredients that allow for the drug to have the desired effect on the body.

The *Guidelines* recommend that “[t]he preparation of pharmaceutical compositions (formulations) requires the use of techniques and compounds commonly known to a person skilled in that field. Patent applications on

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compositions will normally confront an objection of lack of inventive step.”²² The *Guidelines* fail to take into account the extremely large number of potential reformulations that are possible, and the sometimes dramatic improvements in safety and/or efficacy that can be achieved by an innovative new formulation of an existing drug. As correctly observed by the Court of Appeals for the Federal Circuit, “swapping ingredients in complex chemical formulations is anything but ‘routine.’”²³ In recent years, courts in the US, United Kingdom, Germany, Norway, and the Netherlands have all found patents directed towards new formulations of existing drugs to be nonobvious.

b. Doses

A drug can provide a therapeutic benefit only when administered in the right way at the right times. Determining the right dose amounts and frequency necessarily requires high-risk clinical research in humans. There is no industrially applicable drug product without a useful way to use the product. Furthermore, ongoing research may find that while a previous dosing regimen was acceptable, a different dosing regimen may be superior. Nevertheless, the *Guidelines* assert that product claims directed towards “the dose of a drug fail to comply with the industrial applicability requirement.”²⁴

To the contrary, however, new dosages can have dramatic effects on the safety and efficacy of drugs, and investment in researching and developing new and improved dosages of existing drugs should not be discouraged by a blanket prohibition on patent protection for any resulting product. Discouraging this research could prevent the development and commercialization of superior products. For example, a product was substantially improved by lowering the dose

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of the drug administered, thereby reducing side effects, while increasing the concentration of a preservative that increased bioavailability of the drug.²⁵

c. Combinations

The *Guidelines* assert that a patent claim directed towards a combination of two or more known drugs in a single product should be considered lacking in novelty “when the combination was previously known and practiced by the medical profession,” and obvious if the combination does not provide an unexpected synergistic effect.²⁶ In fact, there are good policy rationales supporting the availability of patent protection for inventive combination products, particularly, but not exclusively, when the combination results in a synergistic effect.

Patents provide an incentive for innovators to discover combination products that provide improved therapeutic outcomes compared to either individual active ingredients, and perhaps even more significantly, to fund the expensive human clinical trials necessary to verify and validate the clinical benefits of the combination. At the same time, a claim limited to the combination product in no way precludes patients and doctors from availing themselves to the combination, so long as they administer the drugs separately rather than in a single dosage.

The benefits of combination products are well known and have been documented. For example, studies have shown that patient adherence and compliance can be significantly improved by use of a combination product compared to multiple medications taken individually.²⁷ Combination products improve patient compliance in part by reducing the pill burden of patients. Note that pill burden is not only the number of pills that need to be taken, but also the associated burdens such as keeping track of several medications, understanding their various instructions, etc.²⁸ These products have been widely adopted for illnesses such as diabetes and cardiovascular disease, providing significant advantages over monotherapies, and resulting in improved patient compliance.²⁹

Another advantage arises from the ability to compose combined profiles of, for example, pharmacokinetics, effects, and adverse effects that may be specific for the relative dosages in a given combination product, providing a simpler overview compared to looking at the profiles of each single drug individually. This combined profile can also include effects caused by interaction between the

individual drugs that may be omitted in individual drug profiles. Since combination products are reviewed by regulating agencies (such as the FDA in the United States), the active ingredients used in an approved combination product are unlikely to exhibit adverse drug interactions with each other.

There are numerous judicial decisions from courts in the US and Europe upholding the nonobviousness of combination patents.

d. New medical use

New medical use patents typically cover old molecules used for new diseases. The technical contribution to the art is the method of treating a disease in a novel and inventive way. In many cases, there would be no commercial product without the protection of the use precisely because the molecule is old. Thus, these patents promote the kind of research that can lead to new and useful products.

The *Guidelines* recommend that claims relating to the new use of a known drug be rejected on various grounds, including lack of novelty/invention and absence of industrial applicability.³⁰ The *Guidelines* specifically points to AZT (zidovudine) as an example of a “new medical use,” based on the fact that the drug was initially studied as a potential cancer drug, but after further research and development was shown to be useful in the treatment of HIV.³¹ While the *Guidelines* extol the virtues of AZT as a “drug effective in both the treatment of AIDS and the reduction of mother-to-child transmission,” and as the “first breakthrough in AIDS therapy,” they fail to recognize the role the availability of patent protection for new medical uses played in transforming AZT from a failed cancer drug to a breakthrough in AIDS treatment.³²

AZT would in all likelihood never been developed as an AIDS drug were it not for a team of researchers at Burroughs-Wellcome (a pharmaceutical company) setting up a collaboration with the National Cancer Institute (NCI) to screen the company’s chemical library for compounds having the potential to inhibit HIV replication.³³ While *in vitro* and Phase I clinical trial results indicated that AZT could be safely administered to patients, and that it showed “strong evidence of clinical effectiveness,” it was necessary for Burroughs-Wellcome to conduct a “rigorously maintained double-blind, placebo-controlled randomized trial” as a prerequisite for FDA approval. Without the availability of patent protection for this new

The Guidelines fail to take into account the sometimes dramatic improvements in safety and/or efficacy that can be achieved by an innovative new formulation of an existing drug.

medical use of an old compound, it is very unlikely that AZT would have ever become an AIDS drug.³⁴

In addition to the restrictive use of standard patentability doctrines, the *Guidelines* go further to suggest directly prohibiting methods of medical treatment *per se*. For the reasons just discussed, this would dramatically undermine the research and possibility for new products supported by these patents. Where concerns exist about whether a particular use is sufficiently novel and inventive, the standard tools of patentability are sufficient to determine whether a patent should be issued.

Conclusion

Given the important role pharmaceuticals play in improving the human condition, and the extremely high cost and risk associated with developing new and improved pharmaceuticals, it is critically important that the law not impose overly strict requirements of patentability. To do so risks reducing the incentive for future innovation, and ultimately impoverishing the pipeline for the next generation of drugs. A UK court captured the concern nicely in its recent opinion in *MedImmune v. Novartis* when it stated that:

One of the matters which it may be appropriate to take into account is whether it was obvious to try a particular route to an improved product or process. There may be no certainty of success but the skilled person might nevertheless assess the prospects of success as being sufficient to warrant a trial. In some circumstances this may be sufficient to render an invention obvious. On the other hand, there are areas of technology such as pharmaceuticals and biotechnology which are heavily dependent on research, and where workers are faced with many possible avenues to explore but have little idea if any one of them will prove fruitful. Nevertheless they do pursue them in the hope that they will find new and

In many cases, there would be no commercial product without patent protection for the use precisely because the molecule is old.

useful products. They plainly would not carry out this work if the prospects of success were so low as not to make them worthwhile. But denial of patent protection in all such cases would act as a significant deterrent to research.³⁵

Considered in the abstract, it is easy to devalue the inventiveness of the categories of pharmaceutical innovation targeted by the *Guidelines*. However, as illustrated by the decisions surveyed in this Policy Brief, when courts delve deeply into the substance of these inventions, they are often struck by the unpredictability and difficulty inherent in pharmaceutical innovation. It is hoped that this Policy Brief and the full-length version, *In Defense of Secondary Pharmaceutical Patents: A Response to the UN's Guidelines for Pharmaceutical Patent Examination*, will provide some counterweight to balance some of the more radical, and in my view unwarranted, recommendations set forth in the *Guidelines*.

ENDNOTES

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 - 2 Carlos M. Correa, *Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective*, United Nations Development Programme (2015) [hereinafter the “*Guidelines*”], available at <http://www.ip-watch.org/2016/06/15/un-development-agency-issues-guidelines-for-pharmaceutical-patent-examiners/>.
 - 3 *Id.*
 - 4 Doha Declaration on the TRIPS Agreement and Public Health.
 - 5 Section 3(d) of India’s Amended Patents Act of 2005.
 - 6 *See generally*, World Intellectual Property Organization (WIPO) Committee on Development Intellectual Property (CDIP), *Study of Pharmaceutical Patents in Chile* at 1, n. 6 (2012) (“In Brazil, Article 3 of Bill No. H.R. 5402/2013 proposes to explicitly exclude new uses and new forms of existing medicines (including salts, esters, ethers, polymorphs, metabolites, isomers etc.) from what is considered an invention. South Africa’s Draft National Policy on Intellectual Property released in 2013 proposes similar provisions.”).
 - 7 ICTSD, WHO, UNCTAD, *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective – Working Paper* (2006) at vii.
 - 8 *See, e.g.*, G. Velásquez, *Guidelines on Patentability and Access to Medicines*, South Centre Research Papers No. 61 (2015) (citing commentary from parties such as the Minister of Health of Argentina, Secretary-General of Thailand’s Food and Drug Administration, and the Minister of Health of Brazil, expressing gratitude, appreciation, and congratulations to the WHO for drafting and publication of the *Guidelines*).
 - 9 Christopher M. Holman, *In Defense of Secondary Pharmaceutical Patents: A Response to the UN’s Guidelines for Pharmaceutical Patent Examination*, 50 Ind. L. Rev. 759 (2017), available at <http://ssrn.com/abstract=2833983>.
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 - 11 *Guidelines* at 23.
 - 12 *Id.* at 23-25.
 - 13 *Id.* at 27.
 - 14 *See, e.g.*, Glaxo Grp. Ltd. v. Apotex, Inc., 376 F.3d 1339, 1342-43 (Fed. Cir. 2004).

15 *Guidelines* at 27.

16 *Id.* at 29.

17 *Id.* at 32.

18 *Id.* at 40.

19 *Id.* at 41.

20 Schering Corp. v. Geneva Pharm., 339 F.3d 1373 (Fed. Cir. 2003).

21 *Id.* at 1381.

22 *Guidelines* at 36.

23 Intendis GMBH v. Glenmark Pharm. Inc., USA, 822 F.3d 1355, 1366 (Fed. Cir. 2016) (quotations and citation omitted).

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25 See Allergan, Inc. v. Sandoz Inc., 796 F.3d 1293, 1306 (Fed. Cir. 2015).

26 *Guidelines* at 39.

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28 Roger Collier, “Reducing the “pill burden” “[1], CMAJ February 7, 2012 vol. 184 no. 2. First published January 9, 2012, doi: 10.1503/cmaj.109-4076.

29 D.S. Bell, *Combine and conquer: advantages and disadvantages of fixed-dose combination therapy*, 15 Diabetes Obes Metab. 291 (2013).

30 *Guidelines* at 44.

31 *Id.* at 42.

32 *Id.*

33 See Wikipedia, *Zidovudine*, <https://en.wikipedia.org/wiki/Zidovudine#History>.

34 *Id.*

35 Medimmune v. Novartis [2012] EWCA Civ 1234.

ABOUT THE AUTHOR

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