

# Everything New Is Old Again: Patentable Novelty of Nanoscale Chemical Materials Does Not Imply Newness Under the TSCA and the FDCA

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## ABSTRACT

*Nanotechnology poses special problems for assessing novelty and newness in the patent and in the health and safety regulatory contexts because many engineered nanoscale chemical materials are similar to, if not exactly the same as, their micro- or larger-sized counterparts. A manufacturer will sometimes argue that an engineered nanoscale chemical is “new” for patent purposes but not for other federal regulatory purposes. Whether its claim succeeds depends on whether the definition of new is the same under the Patent Act (which governs “novel” inventions) as it is under the TSCA and FDCA (which govern “new chemical substances” and “new drugs,” respectively). This article investigates what it means to be “new” in the patent, TSCA, and FDCA contexts with respect to engineered nanoscale chemical materials. This article concludes that there is a difference between patentable novelty and novelty for regulatory purposes because the statutes and regulations at issue are designed to accomplish different goals. Therefore, patentable novelty cannot be used as a measure of whether a substance is new for health and safety regulation purposes.*

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## I. INTRODUCTION

Some manufacturers of nanoscale engineered chemical substances claim that when it comes to regulating their products, everything new is old again. They often assert that their products, nanoscale versions of existing drugs and chemicals, are “novel” and deserve patent protection. At the same time, some argue that because the micro- or larger-size versions of the drugs or chemicals are already regulated, the products are not “new chemicals” or “new drugs” under the EPA Toxic Substances Control Act (TSCA) or the FDA Food, Drug, and Cosmetics Act (FDCA) respectively and, therefore, should not be subject to additional health and safety regulations as new substances.

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A number of environmental, health, and consumer advocacy groups contend that this ambivalence is unfair and that the U.S. patent framework strongly supports the conclusion that an issued patent “believes any claim that . . . engineered nanoparticles are not wholly unique substances which must be viewed as new substances [for regulatory purposes].”<sup>1</sup> An issued patent on a nanoscale substance, they argue, means that the U.S. Patent and Trademark Office (USPTO) recognizes the substance to be a novel product. Consequently, these groups urge the FDA and the EPA to “recognize this legal reality and treat these substances as new drugs or new chemicals with new dangers and [subject] their manufacturers . . . to regulation.”<sup>2</sup>

An example of an engineered chemical substance presently generating some controversy is nanoscale zinc oxide (NZO). Zinc oxide has long been a popular over-the-counter (OTC) sunscreen ingredient. However, consumers dislike the chalky-white residue zinc oxide sunscreens leave on the skin.<sup>3</sup> In response, companies such as BASF<sup>4</sup> and Nanophase Technologies<sup>5</sup> have developed zinc oxide particles less than 100 nanometers (nm) across for use in sunscreens.<sup>6</sup> The new NZO formulations have the same chemical compositions as the old sunscreens, but the smaller particle sizes make them appear clear on the skin.<sup>7</sup> The USPTO has issued patents on sunscreens formulated with these NZO products.<sup>8</sup> Nevertheless, when sunscreen manufacturers sought to introduce the new formulations in the marketplace, the FDA did not consider them to be new drugs for marketing approval purposes. Instead, the FDA approved the NZO formulations as OTC drugs because larger-scale zinc oxide was already

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<sup>1</sup> INT’L CTR. FOR TECH. ASSESSMENT, CITIZEN PETITION TO THE UNITED STATES FOOD AND DRUG ADMINISTRATION 64–68 (May 16, 2006), available at <http://www.fda.gov/ohrms/dockets/dockets/06p0210/06p-0210-cp00001-01-vol1.pdf> [hereinafter ICTA Petition]; see also Press Release, Action Group on Erosion, Tech. & Concentration, EPA’s Nanotech Regs: Ironic Parameters: Clean-Up—Clam-Up—Screw-Up? 1–2 (Oct. 18, 2006), available at [http://www.etcgroup.org/upload/publication/595/01/nr\\_epananochemicals\\_061018.pdf](http://www.etcgroup.org/upload/publication/595/01/nr_epananochemicals_061018.pdf); NATURAL RES. DEF. COUNCIL, ET AL., NRDC AND OTHERS COMMENT ON EPA PROPOSAL TO REGULATE NANOMATERIALS THROUGH A VOLUNTARY PILOT PROGRAM 11–12 (2005), available at <http://www.icta.org/doc/OPPT-2004-0122-0037.pdf>.

<sup>2</sup> ICTA Citizen Petition at 68.

<sup>3</sup> All is not vanity because sun damage is not limited to days at the beach. Most occurs because of cumulative exposure throughout the day, walking to and from one’s car, and ultraviolet rays can even travel through automotive glass. Most dermatologists recommend that people apply sunscreen to protect themselves from cumulative sun exposure throughout the day. Skin Cancer and Sun Exposure – From the Cleveland Clinic, available at <http://www.webmd.com/skin-beauty/guide/sun-exposure-skin-cancer> (last visited Apr. 22, 2007). Inorganic sunscreens like zinc oxide are unlikely to cause allergic reactions with sensitive skin and are very effective at blocking harmful ultraviolet radiation, including UVA radiation. Skin Protection – UNH Health Services, available at [http://www.unh.edu/health-services/self-care\\_skin.html](http://www.unh.edu/health-services/self-care_skin.html) (last visited Apr. 22, 2007). However, they result in a very noticeable white residue on the skin. Consequently, many consumers are forced to choose between damaging sun exposure and an embarrassing residue on their skin at the workplace or as they run errands. NZO decreases the white hazy appearance and may encourage more consumers to protect their skin.

<sup>4</sup> BASF Group, *BASF - The Chemical Company*, available at <http://www.basf.com> (last visited Apr. 22, 2007).

<sup>5</sup> Nanophase Technologies, *Nanomaterials and Nanotechnology Leader*, available at <http://www.nanophase.com> (last visited Apr. 22, 2007).

<sup>6</sup> E.g., Sheldon R. Pinnell et al., *Microfine Zinc Oxide Is a Superior Sunscreen Ingredient to Microfine Titanium Dioxide*, 26 DERMATOLOGIC SURGERY 309, 309–10 (2000) (reporting that BASF’s Z-COTE® HPI product has an average particle size of approximately 100 nm); see also BASF Cosmetic Solutions :: Z-COTE®, available at <http://www.cosmetics.basf.de/products.aspx?GrpID=246> (last visited Apr. 22, 2007); Nanophase Technologies: Nanoparticles, NanoGard Zinc Oxide, USP, available at [http://www.nanophase.com/catalog/item.asp?DEPARTME NT\\_ID=38& ITEM\\_ID=41](http://www.nanophase.com/catalog/item.asp?DEPARTME NT_ID=38& ITEM_ID=41) (last visited Apr. 22, 2007) (reporting that a Nanophase Technologies NZO product called NanoGard® Zinc Oxide, USP, has an average particle size of 60 nm).

<sup>7</sup> Gary Stix, *Little Big Science*, SCI. AM., Sept. 2001, at 32, 35.

<sup>8</sup> E.g., U.S. Patent No. 5,587,148 (filed Aug. 4, 1994) (issued Dec. 24, 1996) (a reexamination certificate issued November 20, 2001, confirmed the patentability of all claims).

generally recognized as safe and effective for use as an OTC sunscreen ingredient.<sup>9</sup> Some advocacy groups argue that because the USPTO considers NZO sunscreens to be novel, this finding should be imported to the FDA's assessment, and NZO sunscreens should be treated as new drugs under the FDCA.<sup>10</sup>

This article argues that these regulatory regimes are designed to accomplish different things and so may use the word "new" for entirely different purposes.<sup>11</sup> Part II introduces the definition of patentable novelty, its policy underpinnings, and the USPTO's application of patentable novelty to engineered nanoscale chemical substances. Next, this article discusses the meaning of "new chemical substance" under the TSCA, the implications of a substance being considered a new chemical substance for marketing purposes, and how engineered nanoscale chemical substances are presently classified under the TSCA. This section concludes with a discussion of the meaning of "new drug" under the FDCA, the consequences of a substance being considered a new drug, and how engineered nanoscale chemical substances are currently regulated under the FDCA. Part III discusses the dichotomy between patentable novelty and newness for regulatory purposes. Part IV concludes that the statutes at issue are designed to accomplish different goals, and consequently what is a new drug for patentability purposes is quite different from what may be a new chemical substance or new drug for purposes of regulatory marketing approval. Notwithstanding the advocacy groups' arguments, therefore, patentable novelty should not be imputed to "newness" for purposes of health and safety regulation of engineered nanoscale chemical substances.

## II. BACKGROUND

### 1. Patents

If an invention has been described in a printed publication anywhere in the world, or if it has been in public use or on sale in the United States before the date that an applicant made her invention, the applicant cannot obtain a patent because the invention has been anticipated—in short, it lacks *novelty*. The novelty requirement of the Patent Act makes certain not only that patentees add something new to the store of public knowledge, but also that they do not remove information from the public domain with their claims. Consistent with this policy, the USPTO generally recognizes that nanoscale substances can be novel on the basis of their size alone.

#### A. Patentable Novelty

Section 101 of the Patent Act requires that a patentable invention be "new."<sup>12</sup> An invention may be intrinsically new or a new improvement of an old thing by which the same result is more easily obtained, or a better result secured.<sup>13</sup> The meaning of "new" is defined by three conditions in section 102.<sup>14</sup> Section 102(a) precludes a patent on an invention "known or used by others in this country, or patented or

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<sup>9</sup> Transcript: Public Meeting on Nanotechnology Materials in FDA Regulated Products (Oct. 10, 2006), available at <http://www.fda.gov/nanotechnology/meetings/transcript.html>.

<sup>10</sup> See notes 1 and 2, *supra*, and accompanying text.

<sup>11</sup> It is important to understand at the outset that this article focuses on nanomaterial products—specifically, the nanoscale versions of existing macro- or larger-scale chemicals—and the advocacy groups' argument that a patent on a nanoscale product means that the product is patentably novel and that manufacturers cannot then argue that their nanoscale products are not new chemicals or new drugs under the TSCA and FDCA, respectively. It is another question whether a method claim on a nanomaterial, perhaps a method of making or using the nanoscale chemical, speaks to whether that material deserves regulation as a new use under TSCA or the FDCA. That discussion is outside the scope of this article.

<sup>12</sup> 35 U.S.C. § 101 (2000).

<sup>13</sup> Charles L. Clarke, *Patents, Part III*, 16 GEN. ELECTRIC REV. 799, 799 (1914).

<sup>14</sup> 35 U.S.C. § 102 (2000).

described in a printed publication [anywhere in the world], before the invention thereof by the applicant for patent.”<sup>15</sup> Section 102(e) bars a patent on an invention described in a published patent application or a patent “by another filed in the United States before the invention thereof by the applicant for patent.”<sup>16</sup> Finally, section 102(g) prohibits a patent on an invention that “before [a person’s] invention thereof . . . was made in [the United States] by another inventor who had not abandoned, suppressed, or concealed it.”<sup>17</sup> These three conditions act primarily in a negative fashion; that is, the USPTO presumes that an applicant’s invention is novel under section 102 unless the patent examiner can find a single reference (or use) as described in sections 102(a), (e), or (g) that contains all elements, features, or steps of the claimed invention.<sup>18</sup> The term “novelty” is commonly used to designate patentable newness.

Prior use, knowledge, or disclosure of art which renders a patent (or patent application) invalid based on lack of novelty is said to “anticipate” or even “inherently anticipate” the latter disclosure. Where a single prior-art reference discloses all the elements of a subsequently claimed invention, the reference is said to anticipate the claimed invention.<sup>19</sup> Sometimes, a prior-art reference falls just short of explicitly describing all of the limitations of the claimed invention. But despite the lack of an express disclosure, if the missing aspect *necessarily* results from practicing the subject matter explicitly disclosed in the reference, the law will consider the missing aspect inherently present.<sup>20</sup> Where the combination of the expressly disclosed subject matter and the inherently disclosed subject matter meets each claim limitation of a later-claimed invention, the reference inherently anticipates the later-claimed invention.<sup>21</sup>

## B. Novelty Policy

The overarching purpose of the patent system is to create “new knowledge,”<sup>22</sup> that is, to advance the progress of useful arts.<sup>23</sup> It is commonly observed that the novelty requirement serves this purpose by ensuring that (1) the public receives new knowledge in exchange for the grant of a legal monopoly, and (2) the legal monopoly does not deprive the public of knowledge it already had.<sup>24</sup>

The novelty requirement makes certain that the public gets something new in exchange for an inventor’s legal monopoly. This is important for two reasons. First, like economic monopolies, legal monopolies can carry with them social costs, often “reduced output and higher prices.”<sup>25</sup> The novelty requirement ensures that the public actually receives a social benefit—new knowledge—in exchange for

<sup>15</sup> *Id.* § 102(a) (emphasis added).

<sup>16</sup> *Id.* § 102(e) (emphasis added).

<sup>17</sup> *Id.* § 102(g).

<sup>18</sup> *See* E.I. Du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1434–36 (Fed. Cir. 1988).

<sup>19</sup> Chisum on Patents § 3.02[1].

<sup>20</sup> *E.g.*, *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986).

<sup>21</sup> *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373 (Fed. Cir. 2003).

<sup>22</sup> *See* *Graham v. John Deere Co.*, 383 U.S. 1, 9 (1966) (citing THOMAS JEFFERSON, 6 WRITINGS OF THOMAS JEFFERSON 180–81 (Andrew A. Lipscomb et al. eds., 1905)).

<sup>23</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>24</sup> PHILIP W. GRUBB, PATENTS IN CHEMISTRY AND BIOTECHNOLOGY 3 (1986); CATHERINE COLSTON & KIRSTY MIDDLETON, MODERN INTELLECTUAL PROPERTY LAW 151 (2005) (describing an analogous rationale in the British patent system).

<sup>25</sup> PHILIP AREEDA & LOUIS KAPLOW, ANTITRUST ANALYSIS 150 (Aspen Law & Bus. 5th ed. 1997) (1967); *see also* Chisum on Patents § 3.01. Inflated prices, over-investment, and reduced output are potential (and likely) consequences of a legal monopoly just as in an economic monopoly situation. *See* *Cover v. Hydramatic Packing Co.*, 83 F.3d 1390, 1392–93 (Fed. Cir. 1996) (citing RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 36–37 (3d ed. 1986) (1973)); RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 295–308 (Aspen Law & Bus. 5th ed. 1998) (1973). “The patent system seeks to maintain an efficient balance between the incentives to create and commercialize and the public costs [embodied] in these incentives.” *Id.* at 1392.

the social costs of the legal monopoly.<sup>26</sup> Second, if a patent were granted for something already known, then the patentee would receive a reward for inventing nothing new and disclosing nothing new.<sup>27</sup> Therefore, not only does the novelty requirement ensure that some social benefit exists before imposing the social costs of a legal monopoly, but it also ensures that the fundamental purpose of the Patent Act—to reward invention and disclosure—is satisfied.

Independent of this first theory, if the public at large already knew of the information disclosed and claimed in a patent application and were free to use it, then the later grant of a patent on that knowledge would deprive the public of material to which it already had access and render illegal that to which it already had been entitled.<sup>28</sup> Novelty guarantees that information already within the public domain, available for public use, and within the public's knowledge remains that way.<sup>29</sup>

Judge Rich described these two limitations as encouraging the “good monopoly” and precluding the “bad monopoly”: “[T]he good monopoly or patent is one which serves to give the public, through its incentive, something which it has not had before . . . . The bad monopoly is one which takes from the public that which it already has . . . .”<sup>30</sup> The simple way of ensuring that a patent gives the public new knowledge (the good monopoly) and that a patent does not deprive the public of knowledge it already has (the bad monopoly) is to require that a patentable invention be new to the public and not already expressly or inherently within its grasp.

Yet the solution is not really so simple: novelty alone cannot entirely distinguish good monopolies from bad monopolies and satisfy the careful balance between them. “The slightest change in a useful device, by way of modification or improvement,” Judge Rich observed, “leaves it a useful device and likewise *makes it something new*.”<sup>31</sup> This view is entirely consistent with Thomas Jefferson's comments on the 1790 Patent Act<sup>32</sup> as well as modern federal case law on the matter.<sup>33</sup> If novelty alone were the metric of patentability, patents could reward inventors for giving the public something slightly different from what existed before, but something the public would be quite likely to get anyway without the incentive—a high-quartered shoe instead of a low one; a round hat instead of a three-square; or a square bucket instead of a round one.”<sup>34</sup> That is why prior to 1952, all courts imposed some additional “inventive novelty” requirement for patentability under common law.<sup>35</sup> And that is why, in 1952, Congress added the statutory “nonobviousness” requirement to the Patent Act in section 103, codifying this court-made standard.

In this way, a patent on a novel and non-obvious invention gives the public, through its incentive, not only something which it has not had before, *but also* something it would not be likely to get without

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<sup>26</sup> See *Dewey & Almy Chem. Co. v. Mimex Co.*, 124 F.2d 986, 990 (2d Cir. 1942) (L. Hand, J.) (noting that novelty ensures that patents are only granted to inventions that “enrich the store of common knowledge”).

<sup>27</sup> GRUBB, *supra* note 24, at 3 (describing an analogous rationale in the British patent system).

<sup>28</sup> See *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966); see also CATHERINE COLSTON, *PRINCIPLES IN INTELLECTUAL PROPERTY LAW* 86 (1999) (describing an analogous rationale in the British patent system).

<sup>29</sup> See *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 156 (1989) (observing that novelty is “grounded in the notion that concepts within the public grasp . . . are the tools of creation available to all”).

<sup>30</sup> Giles S. Rich, *Escaping the Tyranny of Words—Is Evolution in Thinking Impossible?*, 60 J. PAT. OFF. SOC'Y 271, 288–89 (1978).

<sup>31</sup> *Id.* at 287 (emphasis added).

<sup>32</sup> See P.J. Federico, *Operation of the Patent Act of 1780*, 18 J. PAT. OFF. SOC'Y 237, 241 (1937) (quoting Thomas Jefferson, Letter to Benjamin Vaughan (June 27, 1790)). A discovery, Jefferson observed, could be new, yet at the same time be “trifling.” *Id.*

<sup>33</sup> See, e.g., *In re Rose*, 220 F.2d 459, 464 (C.C.P.A. 1955) (conceding that an applicant's scaled invention was novel).

<sup>34</sup> Federico, *supra* note 32, at 244 (quoting Thomas Jefferson, Letter to Isaac McPherson).

<sup>35</sup> E.g., *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248, 265 (1850).

the incentive—at least not so soon as with it.<sup>36</sup> And such a patent does not take from the public something which it already has *or* could readily have without the added incentive.<sup>37</sup> However, novelty *on its own* merely ensures that a patent grants new knowledge, however slight, to the American public and that a patent does not remove knowledge already within the American public's grasp.

## 2. Nanotechnology Novelty

Consistent with this policy, the USPTO generally recognizes that nanoscale substances can be novel because they are, in some small way (pun intended), different from the prior art.<sup>38</sup> As discussed above, an inventor's disclosure is presumed to be novel, and the patent examiner rebuts this presumption by citing a reference described in sections 102(a), (e), or (g). Such a reference anticipates (or inherently anticipates) the disclosed invention and renders it unpatentable. However, if there is at least one clear difference in the physical properties between the disclosed invention (for example, “[e]lemental silicon formed into nanoparticles of about 1 nm”<sup>39</sup>) and a prior art reference (for example, silicon nanoparticles having a general diameter of about 10 nm<sup>40</sup>), there cannot be anticipation.<sup>41</sup>

Provided it is not claimed too broadly, a nanoscale substance need not be inherently anticipated by the larger-scale version of the substance either. Referring to the preceding example, suppose the prior-art reference did not clearly indicate the exact physical size and referred only generally to silicon nanoparticles smaller than 10 nm in diameter.<sup>42</sup> In this situation, a patent examiner may argue that the nature of the fabrication method used to form those latter particles *inherently* would have produced particles 1 nm in width.<sup>43</sup> For nanoscale substances, an inherency challenge can be avoided by limiting the claim such that the alleged feature would not necessarily result from the prior art manufacturing process.<sup>44</sup> In this way, the invention could withstand a section 102 rejection for lack of novelty because no prior art reference either anticipates or inherently anticipates the invention.<sup>45</sup>

## III. TSCA

The TSCA provides the EPA with the authority to regulate chemicals before and during their commercialization. The TSCA was intended to address the health or environmental risks from new

<sup>36</sup> Rich, *supra* note 30, at 289.

<sup>37</sup> *Id.*

<sup>38</sup> The USPTO has issued many patents on nanoscale versions of micro- or larger-scaled chemical substances, and many are presently pending before it. *See, e.g.*, U.S. Patent Application Nos. 11/070,617 (filed Mar. 2, 2005); 10/558,333 (filed May 20, 2004); 10/840,660 (filed May 7, 2004); 10/680,872 (filed Oct. 7, 2003); 10/069,640 (filed May 6, 2002); 09/992,713 (filed Nov. 19, 2001); U.S. Patent Nos. 6,746,508 (filed July 18, 2002); 6,432,526 (filed Nov. 19, 2001); 6,878,676 (filed May 8, 2001); 6,585,822 (filed Jan. 5, 2001); 6,329,058 (filed May 27, 1999); 6,136,061 (filed Dec. 1, 1995).

<sup>39</sup> U.S. Patent No. 6,846,474 (filed Feb. 7, 2003).

<sup>40</sup> U.S. Patent No. 5,852,306 (filed Jan. 29, 1997).

<sup>41</sup> Vivek Koppikar et al., *Current Trends in Nanotech Patents: A View From Inside the Patent Office*, 1 NANOTECH. L. & BUS. 5 (2004).

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> *E.g.*, Robert A. Matthews, Jr. & Louis M. Troilo, *Schering Corp. v. Geneva Pharmaceuticals, Inc.: Just How Far Can Inherent Anticipation Extend?*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 779 (2004).

<sup>45</sup> However, even though scaling may render an invention novel, it may be an obvious change in view of the prior art. *In re Rose*, 220 F.2d 459, 464 (C.C.P.A. 1955). Commentators agree that the more difficult question with respect to nanoscale chemicals is not novelty, but rather nonobviousness. *E.g.*, Koppikar et al., *supra* note 41; John C. Miller & Drew L. Harris, *The Carbon Nanotube Patent Landscape*, 3 NANOTECH. L. & BUS. 427 (2006); R. Scott Roe, *Nanotechnology: When Making Something Smaller is Nonobvious*, 12 B.U.J. SCI. & TECH. L. 127 (2006); Terry K. Tullis, Note, *Current Intellectual Property Issues in Nanotechnology*, 2004 UCLA J.L. & TECH. 12 (2004); Michael P. Williams, *Questions Abound About Patents and Nanotechnology*, N.Y. L.J., Sept. 15, 2003, at T7.

chemical products. Based on the language of the TSCA and prior EPA pronouncements and actions, most nanomaterial manufacturers today reasonably do not consider their nanoscale versions of existing micro- or larger-scale chemical substances to be new chemical substances under the Act.

## 1. Authority to Regulate New Chemicals

Human beings and the environment are exposed to numerous chemical substances which may cause or contribute to an unreasonable risk of injury.<sup>46</sup> Congress believed that manufacturers should be responsible for developing adequate data with respect to these chemicals and that the government should have adequate authority to appropriately regulate these substances without impeding or unduly creating unnecessary economic barriers to technological innovation.<sup>47</sup> Consistent with its policy objectives, Congress enacted the TSCA in 1976 to provide the EPA with the authority to establish a regulatory framework governing “chemical substances.” This legislation was intended to “prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances.”<sup>48</sup>

Under the TSCA, a chemical substance is generally “any organic or inorganic substance of a particular molecular identity.”<sup>49</sup> The EPA has the authority to assess the risks of *new* chemical substances and to impose limitations on their manufacture, processing, distribution, and use.<sup>50</sup> A new chemical substance is defined by statute to mean any chemical substance that is not already included on the TSCA Inventory.<sup>51</sup>

In general, before a new chemical substance can be manufactured its manufacturer must comply with the TSCA’s “Pre-Market Notification” (PMN) requirements.<sup>52</sup> A person who intends to manufacture the new chemical substance must submit certain information for the EPA’s review at least 90 days before manufacturing the chemical.<sup>53</sup> After PMN, the EPA may decide to “plac[e] the chemical substance in the Inventory and allow[] it to be manufactured, processed, and used without limitation; subject[] the chemical substance to certain use restrictions; seek[] more data about the substance before a decision is made; or [impose] a complete prohibition on manufacture.”<sup>54</sup>

## 2. Interpretation of “New” under the TSCA

As mentioned above, TSCA defines a “chemical substance” in terms of its “particular *molecular identity*.”<sup>55</sup> The EPA generally adheres to a strict textual interpretation of this language and does not consider other factors, such as physical or chemical properties, in determining whether a chemical substance is new. The EPA’s emphasis on molecular structure is reflected in the PMN review process.<sup>56</sup>

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<sup>46</sup> S. REP. NO. 94-698 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4491.

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> 15 U.S.C. § 2602(2)(A) (2000). There are a number of statutory exclusions from the definition of “chemical substance,” including, among other things, foods and drugs regulated by the FDA.

<sup>50</sup> *See* 15 U.S.C. § 2604 (2000).

<sup>51</sup> 15 U.S.C. § 2602(9). Title 15 U.S.C. § 2607(b)(1) (2000) requires the EPA to “compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States,” a list known as the TSCA Inventory.

<sup>52</sup> EPA, *What is the TSCA Chemical Substance Inventory - New Chemicals Program* (Sept. 18, 2006), available at <http://www.epa.gov/opptintr/newchems/pubs/invntory.htm>.

<sup>53</sup> 15 U.S.C. § 2604(a)(1).

<sup>54</sup> CHRISTOPHER L. BELL ET AL., AM. BAR ASS’N SECTION OF ENV’T, ENERGY & RES., REGULATION OF NANOSCALE MATERIALS UNDER THE TOXIC SUBSTANCES CONTROL ACT 7 (2006), available at <http://www.abanet.org/environ/nanotech/pdf/TSCA.pdf>.

<sup>55</sup> 15 U.S.C. § 2602(2)(A) (emphasis added).

<sup>56</sup> BELL ET AL., *supra* note 54, at 8.

The initial steps of the PMN review process involve the EPA establishing a complete and accurate chemical name for the substance and determining whether the chemical is already on the Inventory.<sup>57</sup> If the EPA determines, based on the chemical identity of the substance alone, that it is already on the Inventory, the PMN review ceases and the submitter is notified that the chemical can be manufactured in the United States.<sup>58</sup>

Despite the EPA's reliance on chemical identity in the PMN decision process, arguments can be made that the statutory term "particular molecular identity" is sufficiently flexible to allow different physical configurations of the same molecular identity to have unique Inventory entries (thus triggering individual PMN review). For example, the Inventory currently contains separate entries for allotropes of elemental carbon (carbon, diamond, and graphite) and for forms of silicon dioxide (silica, quartz, and cristobalite).<sup>59</sup>

Nevertheless, based on the EPA's pronouncements and actions, manufacturers today reasonably do not consider forms of a substance already on the TSCA Inventory to be new chemical substances, even if those forms possess unique physical and chemical properties. First, the various Inventory entries for carbon and silicon dioxide were accepted mainly or exclusively during the original development of the Inventory, when the EPA added tens of thousands of substances at once and circumstances precluded as thorough a consideration of particular entries as the PMN review process does today. Second, it is unlikely that the EPA will continue to create Inventory entries for new physical or chemical arrangements of chemicals whose molecular identities are already represented. The EPA has declined to add additional forms of silicon dioxide to the Inventory as separate entries.<sup>60</sup> In explaining why, the EPA remarked:

The Agency is aware that silicon dioxide, commonly referred to as silica, occurs and is distributed for commercial purposes in several different forms. Inasmuch as the chemical compositions of the various physical forms are the same, EPA does not consider the different physical forms of silica to be separately reportable under TSCA. For the purposes of TSCA, the various physical forms of silica . . . are all considered to be included under CASRN 7631-86-9, which is on the TSCA Inventory.<sup>61</sup>

This pronouncement accords with *In re Concord Trading Corp.*,<sup>62</sup> which publicly articulated the EPA's modern rule of decision. In that TSCA enforcement action, the EPA asserted that sub-molecular differences between an existing chemical substance (zinc oxide) and a disputed form of the chemical (depleted zinc oxide, DZO) allowed the EPA to treat the latter as new.<sup>63</sup> However, an administrative law judge held that because the molecular identities of zinc oxide and DZO were identical, the EPA was not entitled to a judgment as a matter of law that DZO was a new chemical substance.<sup>64</sup>

In conclusion, despite the existence of legacy entries on the Inventory for various allotropes and forms of carbon and silicon dioxide, the EPA's interpretation of the TSCA's new-chemical-substance language follows a literal reading of the statute and the EPA presently classifies all the physical forms of a particular molecular identity under the same Inventory entry. Thus, new physical forms of a substance

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<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> *Id.* at 10.

<sup>60</sup> *Id.* It declined to add forms of amorphous silica and silica gel. *Id.*

<sup>61</sup> *Id.* (citing Letter from Henry P. Lau, Chief of the Chemical Inventory Section, EPA, to Daniel C. Hakes, 3M (Nov. 19, 1993)).

<sup>62</sup> No. TSCA-94-H-19, 1997 WL 738014 (E.P.A. July 24, 1997).

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

molecularly identical to a substance already on the TSCA Inventory are not presently subject to the PMN process and regulated as new chemical substances.<sup>65</sup>

### 3. TSCA and Nanoscale Chemical Substances

The EPA has the authority to regulate wholly new nanomaterials, like any new chemicals, under the PMN requirements of the TSCA.<sup>66</sup> Nanoscale chemical substances, however, are not *wholly* new—they share an identical or indistinguishable chemical structure as their macro-scale counterparts, although they may differ in primary particle morphology and typical particle size. Based upon on the EPA's modern interpretation of "new chemical substance," therefore, the EPA does not presently consider the unique physical properties associated with nanoscale versions of chemicals already listed on the Inventory and does not require their separate PMN review.<sup>67</sup>

Nanoscale versions of chemicals already listed on the Inventory pose a special challenge to the TSCA regulatory framework because they put the EPA's interpretation of chemical substance (essentially, chemical formula) at odds with the very purpose of the Act (to "prevent unreasonable risks of injury to health or the environment associated with the manufacture . . . of chemical substances"). Ordinarily, the various macroscale chemical isomers of a particular compound pose little or no unique risks of injury to health or the environment. Therefore, the EPA's strict reading of chemical substance to mean chemical formula precludes redundant PMN, in accordance with Congress's directive not to "imped[e] or unduly creat[e] unnecessary economic barriers to technological innovation." However, nanoscale chemicals may have very different physical characteristics and properties than those generally associated with the conventional form of the chemical. These differences may cause the nanoscale materials also to have different risk profiles than their chemically identical brethren.<sup>68</sup> Ignoring the risk profiles of these chemicals seems at odds with the fundamental purpose of the statute. On the other hand, it is often very difficult to distinguish a nanoscale chemical material from its macroscale counterpart. Blanket regulation of nanoscale chemicals based solely upon average particle size thus also runs afoul of the Congressional directive not to unnecessarily create economic barriers to development because it may subject chemical manufacturers to redundant PMN. In this way, nanoscale chemicals are problematic because both failing to regulate them and over-regulating them run afoul of the legislative intent in enacting the TSCA.

A recent memorandum written by the Interim ad Hoc Work Group on Nanoscale Materials from the EPA's National Pollution Prevention and Toxics Advisory Committee proposes a sensible framework for resolving these tensions.<sup>69</sup> The Work Group encourages the EPA to explicitly define "new engineered nanoscale materials"—a different definition from new chemical substances—and consider how these materials should be tracked in the TSCA Inventory.<sup>70</sup> This initiative tailors regulation to risk. The Group also suggests that the EPA institute a voluntary pilot program with incentives for nanoscale chemical manufacturers to participate until new regulations and guidelines are finally set into place and promulgated.<sup>71</sup> This will allow for more time for manufacturers and the public to be provided with notice

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<sup>65</sup> That is not to say however, that they will not be regulated at all. If the substance is being put to a significant new use, then that use will also be subject to regulation under TSCA.

<sup>66</sup> Interim ad Hoc Work Group on Nanoscale Materials National Pollution Prevention and Toxics Advisory Committee, U.S. Env'tl Protection Agency, Overview of Issues for Consideration by NPPTAC, Nov. 9, 2005, at 3 [hereinafter NPPTAC].

<sup>67</sup> BELL ET AL., *supra* note 54, at 12.

<sup>68</sup> See, e.g., Philip Ball, *Nanoparticles in Sun Creams Can Stress Brain Cells*, BIOED ONLINE, June 16, 2006, <http://www.bioedonline.org/news/news.cfm?art=2592>.

<sup>69</sup> NPPTAC, *supra* note 66.

<sup>70</sup> *Id.* at 9.

<sup>71</sup> *Id.* at 4.

of significant changes in existing policies with respect to nanoscale chemicals and allow the opportunity for comment.<sup>72</sup> The deficiencies and recommendations identified in the memorandum imply that the TSCA framework, as it is presently interpreted, does not regulate nanoscale materials as new chemical substances. However, it also implies that sensible regulation is not far off.

#### IV. FDCA

The TSCA, as mentioned earlier, broadly governs chemical substances. However, certain areas were carved out of the TSCA for regulating chemicals under other statutory schemes. In order to market pharmaceutical products (including OTC pharmaceutical products) in the United States, the crucial hurdle is approval by the FDA. The FDA is entrusted with the task of protecting consumers from exposure to adulterated and misbranded food and drug products, and related items and devices, by regulating the manufacture, sale, and availability of such items.<sup>73</sup> While nanoscale chemicals are presently outside the ambit of new chemical substance regulation under TSCA, nanoscale drugs fall under the regulatory jurisdiction of the FDCA.

##### 1. Authority to Regulate New Drugs

Pharmaceutical products, including OTC pharmaceutical products,<sup>74</sup> must be approved by the FDA, the agency which regulates all pharmaceutical products in the United States under the authority granted by Congress in the FDCA. The Act provides a definition for what is a pharmaceutical product or “drug” subject to regulation: “[t]he term ‘drug’ means articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals [by chemical action]”<sup>75</sup> and “articles (other than food) intended to affect the structure or any function of the body of man or other animals.”<sup>76</sup> This definition is interpreted rather loosely. For example, an ordinary person would not consider tanning preparations which contain a sunscreen ingredient to be drugs in the common dictionary sense of the word. Yet, because these preparations aid in the prevention of sunburn, they are considered to be drug products—usually OTC drug products—by the FDA and are regulated accordingly.<sup>77</sup>

The FDCA defines “new drug” to mean one that has not been “generally recognized as safe and effective” (GRASE) for use under the condition prescribed, recommended, or suggested in the labeling thereof among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs.<sup>78</sup> The FDA generally errs on the side of caution when deciding whether to classify a drug as a new drug. For example, generic versions of an approved prescription drug may be considered new under the Act even if the only difference between the products lies in the configuration of their inactive ingredients.<sup>79</sup>

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<sup>72</sup> BELL ET AL., *supra* note 54, at 12 n.19.

<sup>73</sup> FDA’s Mission Statement, *available at* <http://www.fda.gov/opacom/morechoices/mission.html> (last visited Apr. 23, 2007).

<sup>74</sup> OTC drug products are those drugs that are available to consumers without a prescription.

<sup>75</sup> 15 U.S.C. § 55(c)(2) (2000).

<sup>76</sup> *Id.* § 55(c)(3).

<sup>77</sup> Sunscreen Regulations Finalized (May 21, 1999), *available at* <http://www.fda.gov/bbs/topics/ANSWERS/ANS00955.html>.

<sup>78</sup> 21 U.S.C. § 321(p)(1) (2000).

<sup>79</sup> *United States v. Generix Drug Corp.*, 460 U.S. 453 (1983); *see also* *Premo Pharmaceutical Laboratories, Inc. v. United States*, 629 F.2d 795 (2d Cir. 1980); *United States v. Undetermined Quantities of Article of Drug*, 709 F. Supp. 511 (D.N.J. 1987), *aff’d without opinion*, 857 F.2d 1466 (3d Cir. 1987); *United States v. Atropine Sulfate 1.0 mg*, 843 F.2d 860 (5th Cir. 1988).

The FDCA requires that the manufacturer of a new drug complete a New Drug Application (NDA) prior to the drug entering interstate commerce.<sup>80</sup> The first type of application (filed under section 505(b)(1) of the Act) contains the full reports on safety and effectiveness studies. This application proves the safety of a drug, and it is an expensive and complicated proceeding, routinely taking five years for a drug to get approval.<sup>81</sup> The second type (filed under section 505(b)(2)) permits the FDA to rely on literature data or on the Agency's own finding of safety or effectiveness for an approved drug product during the approval process. This type of application speeds the approval process of a new drug considerably. The third type (filed under section 505(j) of the Act), also called an abbreviated new drug application (ANDA), is for products that are bio-equivalent—that is, identical in drug substance, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use—to drugs that have already been approved by the Agency. The ANDA process also speeds the drug to market because the applicant is not required to include preclinical (animal) and clinical (human) data to establish its safety and effectiveness.<sup>82</sup>

The Act exempts from the NDA process any drugs categorized as GRASE.<sup>83</sup> For these drugs, approval is pursuant to an FDA monograph.<sup>84</sup> Such monographs outline the active ingredients that the FDA has found to be safe and effective, based on a history of safe use or scientific evidence.<sup>85</sup>

## 2. Nanotechnology and the FDCA

There are unexpected benefits to formulating a pharmaceutical into a nanoscale formulation. Such benefits include “increased bioavailability, faster onset of action, dose uniformity, reduction in fasted and fed variability, decreased toxicity, smaller dosage form, and stable dosage forms of the drug which could not previously be formulated conventionally.”<sup>86</sup> Given the advantages of formulating a drug product into a nanoscale size, it is not surprising that companies have recently turned to rescaling their drug products.

Consistent with the FDA's mission to ensure that drugs reaching the marketplace are safe and effective, the FDA regulates drugs that use nanotechnology in their formulations. However, the Agency purportedly treats nanomaterial product ingredients no differently than bulk material product ingredients. This is presently subject to some scrutiny, particularly with respect to nanoscale OTC drugs.

A nanoscale drug (like any drug) which has not been categorized as GRASE is subject to the NDA process. Typically, the FDA does not consider nanoscale drugs bioequivalent to their micronized or larger-scale counterparts, and thus ineligible for the ANDA process;<sup>87</sup> nevertheless, manufacturers may rely on safety and toxicity studies of these approved drugs to expedite approval during the section 505(b) NDA approval process. As an example, one of the first nanoscale drugs to wind its way through the NDA process was the Wyeth product Rapamune® (sirolimus),<sup>88</sup> used to prevent kidney transplant rejection.<sup>89</sup>

<sup>80</sup> See generally New Drug Application (NDA) Process (Sept. 6, 2005), available at <http://www.fda.gov/cder/regulatory/applications/nda.htm>.

<sup>81</sup> *Drug Patent Term Restoration Review Procedure Act of 1999*, S. Comm. on the Judiciary, 117th Cong. (1999) (testimony of Richard Jay Kogan).

<sup>82</sup> Abbreviated New Drug Application (ANDA) (Apr. 19, 2006), available at <http://www.fda.gov/cder/regulatory/applications/anda.htm>.

<sup>83</sup> MICHAEL R. TAYLOR, REGULATING THE PRODUCTS OF NANOTECHNOLOGY: DOES FDA HAVE THE TOOLS IT NEEDS 41 (2006), available at [http://nanotechproject.org/file\\_download/110](http://nanotechproject.org/file_download/110).

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

<sup>86</sup> Mary C. Till et al., *Nanotech Meets the FDA: A Success Story About the First Nanoparticulate Drugs Approved by the FDA*, 2 NANOTECH. L. & BUS. 163, 166 (2005).

<sup>87</sup> *Id.*

<sup>88</sup> *Id.* at 164.

<sup>89</sup> Rapamune Consumer Information (Dec. 29, 2004), available at <http://www.fda.gov/cder/consumerinfo/druginfo/rapamune.HTM>.

Rapamune®, originally approved by the FDA on September 15, 1999,<sup>90</sup> was previously available only as an oral solution in bottles or sachets. The oral solution required refrigeration storage, and had to be mixed with water or orange juice prior to administration.<sup>91</sup> Wyeth brought their drug to Elan Pharmaceuticals for development of a nanoscale formulation using Elan's NanoCrystal® Technology—one of the earliest technologies for nanoscaling drugs.<sup>92</sup> The new formulation reduced particle size to less than 200 nm and overcame the drug's relative insolubility allowing it to be administered in tablet form.<sup>93</sup> It also increased the mean bioavailability of sirolimus after administration of the tablet by 27% relative to the oral solution.<sup>94</sup> Wyeth filed a section 505(b) NDA on October 29, 1999, and was able to rely, at least in part, on earlier toxicity studies for the larger-scale version of Rapamune® to obtain approval for the nanoscale version on August 25, 2000.<sup>95</sup> This marked the first commercial launch of a nanoscale drug.

Like new nanoscale drugs subject to the NDA process, nanoscale versions of OTC drugs classified as GRASE also do not currently receive special consideration by the FDA. First, the traditional OTC monograph has not been updated to accommodate nanoscale drugs. Although it requires a list of active ingredients by name and may include purity and other specifications, it makes no reference to material size. Second, the FDA affirmed that “particle size does not affect the classification of these ingredients.”<sup>96</sup> For now, the FDA seems to be satisfied with the studies of the safety and efficacy of nanoscale OTC drugs.<sup>97</sup>

As discussed earlier with respect to the TSCA and nanoscale chemicals, the treatment of nanoscale drugs (and nanoscale OTC drugs in particular) under the FDCA seems to be at odds with the legislative purpose of the statute: to ensure safety and efficacy of drugs. First, the OTC approval process seems to erroneously assume that because the FDA monograph presently does not include particle size, it is irrelevant to product safety. However, studies show that particle size plays a significant role in both a substance's efficacy and its toxicity. Second, it may be inappropriate to apply toxicity data for macroscale drugs when expediting the NDA process for nanoscale counterparts. Macroscale and nanoscale formulations may have marked differences in bioavailability. Thus, the mission of the FDA to

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<sup>90</sup> *Id.*; FDA Approves Rapamune to Prevent Organ Rejection (Sept. 15, 1999), available at <http://www.fda.gov/bbs/topics/ANSWERS/ANS00974.html>.

<sup>91</sup> Patrick McGee, *Delivering on Nano's Promise*, DRUG DISCOVERY & DEVELOPMENT, Oct. 2006, at 12, 14.

<sup>92</sup> *Id.*

<sup>93</sup> Elan, NanoCrystal® Technology, available at [http://www.elan.com/edt/nanocrystal\\_technology/default.asp](http://www.elan.com/edt/nanocrystal_technology/default.asp) (last visited Apr. 23, 2007).

<sup>94</sup> FOOD & DRUG ADMIN., RAPAMUNE® (SIROLIMUS) ORAL SOLUTIONS AND TABLETS 2 (2003), available at <http://www.fda.gov/cder/foi/label/2003/021083s0061bl.pdf>

<sup>95</sup> Letter from Renata Albrecht, FDA Ctr. for Drug Evaluation & Res., to Randall Brenner, Wyeth-Ayerst Res. (Aug. 25, 2000), available at <http://www.fda.gov/cder/ogd/rld/21083s4.PDF>; Correspondence, available at [http://www.fda.gov/cder/foi/nda/2000/21110\\_Rapamune\\_corres.pdf](http://www.fda.gov/cder/foi/nda/2000/21110_Rapamune_corres.pdf).

<sup>96</sup> Andreas von Bubnoff, *Reaction is Mixed to Petition Asking FDA to Recall Sunscreens That Use Nanotechnology*, SMALL TIMES, May 30, 2006, available at [http://www.smalltimes.com/articles/article\\_display.cfm?Section=ARCHI&C=Legal&ARTICLE\\_ID=270665&p=109](http://www.smalltimes.com/articles/article_display.cfm?Section=ARCHI&C=Legal&ARTICLE_ID=270665&p=109).

<sup>97</sup> Nakissa Sadrieh, FDA Office of Pharmaceutical Science, FDA Considerations for Regulation of Nanomaterial Containing Products, [http://www.fda.gov/nanotechnology/powerpoint\\_conversions/NISTHouston0106\\_files/outline](http://www.fda.gov/nanotechnology/powerpoint_conversions/NISTHouston0106_files/outline). John Bailey of the Cosmetic Toiletry and Fragrance Association commented at an FDA public forum: Most uses are limited to [titanium dioxide] and zinc oxide. These are approved drug active ingredients by FDA. The micronized or nano [titanium dioxide] and zinc oxide have been reviewed and found to be safe by FDA. The products are used according to regulation and they provide clear benefit. Any assertion that these products should be pulled from the market fails to take into account the fact that they do prevent skin cancer and are very important public health products and that should be kept in mind. Transcript, *supra* note 10.

ensure safety and efficacy of drugs is to some degree frustrated by its failure to consider particle size in considering whether a product is a “new drug.”

Consequently, the FDCA will likely be well served by *sui generis* treatment of nanotechnology drugs so that regulation will be well tailored to the risks posed by these products. This regulation is probably not far off. Consistent with the FDA’s mission, its Nanotechnology Task Force is currently “determining regulatory approaches that encourage the continued development of innovative, safe, and effective FDA-regulated products that use nanotechnology materials.”<sup>98</sup>

## V. DISCUSSION

Specialized regulations in both the FDCA and TSCA contexts are on the horizon. However, various advocacy groups believe that they cannot come soon enough. These groups argue that an issued patent on an engineered nanoscale chemical or drug means that the U.S. government considers it a novel substance and that this finding should be imputed to health and safety schemes that regulate new substances, namely the TSCA and the FDCA. Ostensibly, this request is meant to serve as a temporary measure for regulating “new chemical substances” and “new drugs” until *sui generis* frameworks can be established. However, there is a statutory distinction between patentable novelty and novelty for drug and chemical marketing approval purposes. The three regimes (the Patent Act, the TSCA, and the FDCA) were designed to accomplish different things and so may use the word “new” for entirely different purposes. Patentable novelty cannot and should not be imported to these frameworks—even temporarily.

### 1. Novel Scaling Does Not Imply Health and Safety Risks

As discussed in Part II above, while the physical properties of a chemical substance (for example, primary particle size, permeability, or catalytic properties) may certainly contribute to its novelty, it is impossible to say whether the government considers them to be the new part of an invention. So long as an invention is different from prior art, then the invention is patentably new. Novelty works in a negative fashion. That is, during examination, the USPTO only states which prior art renders an invention *not* novel. Even when a patent examiner makes a section 102 anticipation rejection that is later overcome by the applicant’s persuasive arguments, the USPTO never conclusively states which parts of an invention it considers to be novel improvements over the prior art. An invention’s new and unexpected physical properties can overcome anticipation problems. However, simple scaling of prior art may *also* render an invention patentably novel<sup>99</sup> if the scaled invention is technically different from what was described in the prior art. The holder of an issued patent can therefore say that her invention is novel, and it certainly may have a host of potentially novel properties, but she cannot say for certain what the government considers to be the invention’s novel parts—it may be scaling alone.

If a patent examiner based a nanoscale chemical’s novelty solely on its scaling of the prior art, importing that patentable novelty into the health and safety regulatory schemes would violate their legislative intent. Congress drafted these frameworks to appropriately regulate potentially harmful substances which may cause or contribute to health and safety risks without impeding or unduly creating unnecessary economic barriers to technological innovation. A scaled chemical does not *necessarily* contribute an unreasonable risk of injury, and imposing blanket regulation on scaled chemicals would almost certainly be an unnecessary economic barrier to technological innovation.

Assume, for example, that an inventor grows ordinary table salt to an extraordinarily large average crystal size, much larger than has ever been observed and described in (or even thought possible by) the

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<sup>98</sup> FDA Nanotechnology Task Force, [http://www.fda.gov/nanotechnology/nano\\_tf.html](http://www.fda.gov/nanotechnology/nano_tf.html) (last visited Apr. 23, 2007).

<sup>99</sup> The scaling improvement itself is likely not sufficiently creative to deserve a patent, however.

prior art. The inventor seeks to patent the product. During prosecution, the patent examiner considers the product to be novel because of the scaling; she does not consider any of the salt's other properties because it would be superfluous to her decision. Assuming for sake of the example that the invention is also useful and nonobvious, a patent eventually issues. Large-crystal table salt is no more dangerous to humans than the salt on one's dinner table and its chemical, physical, and safety properties can be readily inferred. Yet, the advocacy groups' argument that patentable novelty should be imported to the TSCA's definition of a new chemical substance or the FDCA's definition of a new drug would require that the salt be subject to PMN requirements or NDA requirements (assuming counterfactually that salt would be regulated under both schemes). Such a sweeping regulation would be unreasonable in view of the low risk of injury to humans or the environment. Consequently, PMN or NDA regulation based solely on scaling could create unnecessary economic barriers to technological innovation.

Many nanoscale chemicals cause or contribute to at least some risk of injury to both humans and the environment. However, the patentable novelty of nanoscale chemicals is simply not the proper standard to trigger PMN or NDA requirements for them. The legislative intent behind the TSCA and the FDCA requires special consideration of a substance's riskiness, and regulation based upon patentable novelty would be hopelessly overbroad. The advocacy groups' proposal effectively requests that the EPA and the FDA define a chemical substance to be "new" potentially on the basis of crystal size alone (nanosized or not) without consideration of the substances' risks or unique chemical properties.<sup>100</sup> Thus, the proposed rule could erect unnecessary economic barriers by subjecting manufacturers to the PMN or the NDA process even if their patentably new chemical substances pose absolutely no new foreseeable risks. Such a proposal is contrary to the policy grounds of the TSCA and the FDCA and the scope of the agencies' enforcement.<sup>101</sup> The EPA and FDA do not<sup>102</sup> and should not consider that all patentably new forms of a substance are necessarily subject to PMN or NDA requirements.

## 2. Importing Patentable Novelty Will Lead to Undesirable Results

What is a new drug for patentability purposes is not the same as a new drug for purposes of needing FDA marketing approval. The FDCA and the TSCA, as health and safety regulatory schemes, and the Patent Act, meant to create new knowledge, simply serve different purposes.

The advocacy groups argue that a substance that is new under the Patent Act should be subject to health and safety regulation as new drugs or new chemical substances. But this reasoning fails if one applies the negative of this argument: that a substance that is *not* new under the Patent Act should *not* be subject to health and safety regulation under the FDCA or the TSCA. The groups contend that if the government (speaking through the USPTO) deems a nanoscale chemical substance to be new by issuing its inventor a patent, that inventor cannot argue that it is not new under other regulatory schemes. But it is hard to believe these groups would support the conclusion that if the government formally states that a substance is *not* patentably new that it should *not* be subject to regulation—and for good reason. The Patent Act's definition of novelty is not "newness" in its dictionary sense. If a chemical substance, for example, is described in a publication anywhere in the world prior to a patent applicant's date of invention, the substance is not new for patentability purposes. This does not mean that the chemical

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<sup>100</sup> The novelty of a patented engineered nanoscale chemical can be but is not necessarily due to the newness of its physical or chemical properties—the attributes that are most likely to contribute to its health or environmental risks. Micronizing can be a novel improvement. See discussion in Section II.2, *supra*.

<sup>101</sup> This would be particularly undesirable because it would be using the Patent Act against itself. The Patent Act is meant to encourage and reward innovation. See discussion in Section II.1, *supra*. This broad rule would unreasonably punish it.

<sup>102</sup> For example, forms of amorphous silica and silica gel, ostensibly patentable isomers of SiO<sub>2</sub>, were not added to the TSCA Inventory, and their manufacturers were not subject to the PMN process. See notes 60 and 61, *supra*, and accompanying text.

substance does not have unique (and potentially risky) chemical or physical properties. The chemical substance's risks to human health have nothing to do with the fact that it was published elsewhere before a patent applicant's date of invention. In this way, importing patentable novelty into the FDCA's definition of a new drug or the TSCA's definition of a new chemical substance would result in a perverse (and risky) conclusion. They must be independent inquiries.

Second, the groups' argument appears illogical if one simply reverses the order and contends that a substance that is a new drug under the FDCA or a new chemical substance under the TSCA should automatically be considered novel under section 102 of the Patent Act. These statutes each have defined what it is to be new in order to fulfill their own policy goals. Assume, for example, that a pharmaceutical manufacturer wished to patent a chemical its scientists had recently discovered. During examination, the USPTO discovered that this chemical was already described by team of researchers in a medical journal before the manufacturers' chemists had ever thought of it. The examiner rejected the application as anticipated under section 102. Notwithstanding its failure in the Patent Office, the manufacturer wished to market the drug in this country. The FDA informed the manufacturer that its drug would be considered a "new drug" for regulatory purposes and subject to the NDA process. It would be absurd to argue that the manufacturer could present the FDA's finding to the USPTO to overcome the final rejection and obtain the patent. This would violate the plain language of section 102; yet this is effectively what the advocacy groups attempt to argue—that newness in one regulatory scheme satisfies newness in another. The Patent Act and the FDCA were simply designed to accomplish different goals and consequently use "new" for different purposes.

Finally, what is "useful" for patent law purposes may not be "useful" for drug regulatory purposes, an analogous distinction that demonstrates the different purposes of the FDCA and Patent Act statutes. Under the Patent Act, FDA approval is not a prerequisite for finding a drug compound to be "useful"—a statutory requirement of patentability.<sup>103</sup> Likewise, simply because a drug is patentably useful does not mean it will pass clinical trials, requiring FDA regulation. Just as the word novelty has special meaning under the Patent Act, the meaning of "useful" is different from the dictionary sense of the word. Ordinarily, people would not consider a pill that has only been shown to suppress cancer in rats to be terribly useful. Nevertheless, demonstrating that a compound exhibits some desirable pharmaceutical property, such as with experimental animal models, is considered a useful contribution to the art and, therefore, sufficient to establish utility.<sup>104</sup> The policy behind this interpretation is to stimulate invention. If the USPTO were to require successful clinical trials—that is, human testing—in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions. This could eliminate smaller companies' incentive to pursue, through research and development, potential cures in many crucial areas. In this way, utility within the meaning of the patent statute is not equivalent to the standards for approval of a new drug set by the FDA, and the stage at which a pharmaceutical invention can be considered useful is well before it is ready to be administered to humans. The FDCA and the Patent Act serve different purposes and their language simply cannot be imputed to each other.

Again, this is not to say that nanoscale drugs (even OTC drugs like NZO) should not be regulated as new drugs under the FDCA or that nanoscale chemicals should not be regulated as new chemical substances under the TSCA. These regulatory schemes are meant to protect consumers from exposure to dangerous chemical and drug products, and there is plenty of evidence to show that nanoscale formulations of otherwise benign chemicals can have unexpected effects in the human body and the environment. However, the patentable novelty standard cannot be imported into the FDCA and TSCA. It would be a perverse result if a potentially risky nanoscale drug escaped "new drug" status merely because

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<sup>103</sup> 35 U.S.C. § 101 (2000).

<sup>104</sup> *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995).

it was anticipated under section 102 of the Patent Act. These schemes will be better served by sui generis regulation of nanotechnology that tailors its special risks to the burden of regulation.

## **VI. CONCLUSION**

Patentable novelty cannot be imputed to newness standards under other regulatory schemes quite simply because they are all designed to accomplish different goals. This is not to say that patented nanoscale substances should not be regulated under TSCA and the FDCA. On the contrary, both the EPA and FDA recognize that nanoscale substances raise new and substantial risks to health and the environment. For this reason, these agencies are working to develop comprehensive regulations specifically tailored to curtailing the health and safety risks created by the burgeoning nanotechnology industry that do not pose unreasonable restraints on its growth in the United States.

While the USPTO certainly has experience studying the novelty and the unique properties and features of these substances, it is important that its regulatory framework is not imported into the TSCA and the FDCA. The Patent Office's regulations were not developed with any eye toward protecting health and safety. Therefore, until the FDA and the EPA define nanotechnology and its regulation in such a way to best advance their Congressional policy directives, the existing systems—and their definitions of what constitutes a new chemical substance or new drug—will have to suffice. For now, everything new is old again.