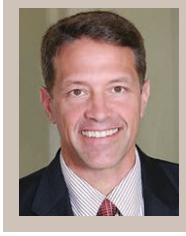
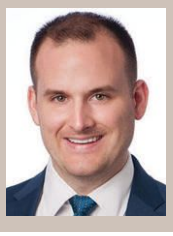
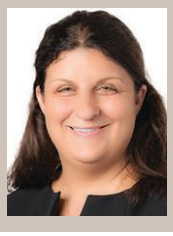
By Brad DeJardin, Connor Scott, Caroline M. Tinsley, and Elizabeth Cummings

It's All in the Form: Asbestiform vs. Non-Asbestiform

In asbestos litigation, the difference between asbestiform and non-asbestiform minerals is typically not addressed, and the parties on either side may not even be aware of this crucial difference. In fact, they are far more likely to argue over *which* of the asbestos minerals are present in their case (whether it was a serpentine mineral—chrysotile, or an amphibole—crocidolite, amosite, tremolite, anthophyllite, or actinolite) than they are to argue *whether* asbestos is present in the products at issue. This is because most typical asbestos litigation, such as that involving friction or insulation products, involves allegations that asbestos was intentionally added to the product. This is not the case with talc litigation. In a talc asbestos case, the central allegation is that the talc that made it to the consumer was *contaminated* with asbestos fibers. Asbestos was never intentionally added to talc as a component part of the finished product, and talc defendants assert that their talc is and always has been asbestos free. For their part, plaintiffs

■ Brad DeJardin, a partner and head of the complex tort division of Dentons' Los Angeles office, defends companies faced with complex tort matters, including product liability, mass tort and premises liability suits. Connor Scott is an associate in Dentons' Los Angeles office, where his practice focuses on product liability and complex torts. Caroline Tinsley, a partner in the medical device and pharmaceutical liability practice group in Tucker Ellis LLP's St. Louis office, defends leading product manufacturers in mass tort and product liability matters across the country. Elizabeth Cummings, counsel at Tucker Ellis LLP's St. Louis office, represents clients in cases involving medical and pharmaceutical liability, toxic tort, and product liability.



and plaintiffs' experts assert that the testing methods used by talc defendants were not sensitive enough (by design) to detect asbestos contamination. These cases then turn on the testimony of plaintiffs' experts who purport to identify asbestos (asbestiform) fibers in talc, and defendants' experts who contend that these very same 'asbestos fibers' are in fact not asbestos at all (non-asbestiform).

Definition of an "Asbestos Fiber"

Asbestos is a "generic term for several hydrated silicates," meaning "chrysotile, amosite, crocidolite, anthophyllite asbestos, tremolite asbestos, and actinolite asbestos." *Metal and Nonmetal Health Inspection Procedures*, in MSHA - Handbook Series - PH06-IV-1(1), 8-1 (2006). Importantly, asbestos is a regulatory and industry term. *Id.* It is not a geological or mineralogical term. An asbestos fiber is one of these six regulated minerals that has a certain size and shape, defined as a "length greater than five microns" by some sources and by aspect ratio in others. *Id.* The mission of the United States Geological Survey is to serve "the Nation by providing reliable scientific information to describe and understand the Earth." USGS, *Who We Are*, https://www.usgs.gov. It defines asbestos as follows:

> The term "asbestos" is not a mineralogical definition. It is a commercial designation for mineral products that possess high tensile strength, flexibility, resistance to chemical and thermal degradation, and high electrical resistance and that can be woven.

USGS, *Some Facts About Asbestos*, http://www.capcoa.org (hereinafter "USGS Facts About Asbestos").

Definition of Asbestiform and Non-Asbestiform

Unlike the term asbestos, the terms "asbestiform" and "non-asbestiform" are mineralogical terms. They refer to the "habit" in which a given mineral crystallizes, which determines whether that mineral is a regulated asbestos mineral or one of its analogues. The EPA defines asbestiform as a type of "morphology" and states that it is "said of a mineral that is like asbestos, *i.e.*, crystallized with the habit of asbestos." R.L. Perkins & B.W. Harvey, Test Method for the Determination of Asbestos in Bulk Building Materials, A-1 (1993). A mineral is crystallized with the habit of asbestos if it has the following characteristics: "[m]ean aspect ratios ranging from 20:1 to 100:1 or higher for fibers longer than 5μm… Very thin fibrils, usually less than .5 microm-

■

Plaintiffs and plaintiffs' experts assert that the testing methods used by talc defendants were not sensitive enough (by design) to detect asbestos contamination.

■

eters in width, and [t]wo or more of the following; parallel fibers occurring in bundles, fiber bundles displaying splayed ends, matter masses of individual fibers, and/or fibers showing curvature." *Id.* Growing in the asbestiform habit means growing "almost exclusively in one dimension," which allows these minerals to be "easily bent." Brooke T. Mossman, *Assessment of the Pathogenic Potential of Asbestiform vs. Nonasbestiform Particulates (Cleavage Fragments) in In Vitro (Cell or Organ Culture) Models and Bioassays,* International Symposium on the Health Hazard Evaluation of Fibrous Particles Associated with Taconite and the Adjacent Duluth Complex (2003), https://ntp.niehs.nih.gov.

Non-asbestiform minerals are chemically similar to asbestiform minerals but do not crystallize in the asbestiform habit and lack the characteristics of asbestiform minerals. When non-asbestiform, these minerals are referred to as mineral fragments or cleavage fragments. This morphological difference is key (at least, according to defendants). According to both the USGS and OSHA, "available evidence supports a conclusion that exposure to *non-asbestiform* cleavage fragments is not likely to produce a significant risk of developing asbestos-related disease." USGS Facts About Asbestos, *citing* 57 Fed. Reg. 24310 (June 8, 1992) (emphasis added). This reference to cleavage fragments is also significant. Unlike asbestiform minerals, non-asbestiform minerals "grow in several directions at once" and "fracture easily into particles called cleavage fragments" instead of bending. (Mossman, *supra*.) While asbestiform minerals splinter into fibers and fibrils, "[i]n the non-asbestiform habit, mineral crystals do not grow in long thin fibers; they grow in a more massive habit." 73 Fed. Reg. 11285 (February 29, 2008). This massive habit means that "when non-fibrous minerals are crushed, as may occur in mining and milling operations," cleavage fragments are formed instead of fibers. *Id.* Therefore, while asbestiform minerals form long thin fibers, non-asbestiform minerals can break into cleavage fragments that are generally shorter, thicker, form along cleavage planes in the mineral, and lack the high strength and flexibility of asbestiform fibers. Brooke T. Mossman, *Assessment of the Pathogenic Potential of Asbestiform vs. Non-asbestiform Particulates (Cleavage Fragments) in In Vitro (Cell Or Organ Culture) Models and Bioassays*, 52 Regul. Toxicol. Pharmacol. (2008), https://www.ncbi.nlm.nih.gov.

At times, non-asbestiform minerals may appear long and thin, resembling asbestiform, however this similar appearance does not change their morphological features. Because the difference between asbestiform and non-asbestiform minerals is in how the minerals were formed, each of the regulated asbestos minerals has a non-asbestiform analogue. These asbestos minerals and their non-asbestiform counterparts are presented in Table 1.

Table 1

Non-Asbestiform	Asbestiform
Anthophyllite	Anthophyllite Asbestos
Tremolite	Tremolite Asbestos
Actinolite	Actinolite Asbestos
Antigorite	Chrysotile
Cummingtonite-grunerite	Amosite
Riebeckite	Crocidolite

Federal Agencies and Standard-Setting Organizations Define Asbestos by Asbestiform Habit

In talc asbestos litigation, the central issue is whether asbestos is present in talc, which then turns into a dispute over whether a specific mineral identified in the talcum powder products is asbestiform or non-asbestiform.

Plaintiffs' counsel will generally provide argument and expert testimony to present the following points:

- Whether the materials are asbestiform or non-asbestiform is a smokescreen and a definition game.
- The human body does not care whether a particle is asbestiform or non-asbestiform once it is in the lung.
- Asbestiform and non-asbestiform particles are chemically identical, therefore non-asbestiform particles are harmful and the same as asbestos.
- Large crystals of non-asbestiform tremolite or anthophyllite may be modified during processing and converted to asbestiform.

Defense counsel will generally attempt to counter these arguments by pointing to the findings and definitions of public health agencies to argue that

- Agencies and experts define asbestos by the "habit" of the mineral, meaning whether the mineral is asbestiform or non-asbestiform.
- There are no peer-reviewed studies showing that non-asbestiform minerals are harmful.
- Non-asbestiform fibers are structurally different from asbestiform fibers, which is more important than chemical similarity. A diamond and a lead pencil are both chemically identical, but structurally different.
- Non-asbestiform is similar to ordinary rock—no matter what one does with it or how it breaks it apart, simply breaking it apart will not convert non-asbestiform into asbestiform because non-asbestiform particles do not crystallize in the specific way that leads to the unique properties of asbestiform.

Because of this dispute, expert discovery and expert testimony is essential to these cases, as are the findings of federal, scientific, and regulatory agencies. Many of these agencies define asbestos as a mineral that formed in the asbestiform habit, as seen below.

Occupational Safety and Health Organization (OSHA)

In 1992, OSHA amended its definition of asbestos to remove the non-asbestiform varieties. In making this change, OSHA stated that it had "reviewed available relevant evidence" and that, "[b]ased on the entire rulemaking record before it, OSHA has made a determination that substantial evidence is lacking to conclude that non-asbestiform tremolite, anthophyllite and actinolite present the same type or magnitude of health effect as asbestos." Occupational Exposure to Asbestos, Tremolite, Anthophyllite and Actinolite, 57 Fed. Reg. 24310-01 (Jun. 8, 1992). OSHA continued to state that "substantial evidence does not support a finding that exposed employees would be at a significant risk because non-asbestiform tremolite, anthophyllite or actinolite was not regulated." *Id*. For these reasons, OSHA amended its asbestos standards to "*remove* non-asbestiform tremolite, anthophyllite and actinolite from their scope." *Id*. (emphasis added).

In talc asbestos litigation, the central issue is whether asbestos is present in talc, which then turns into a dispute over whether a specific mineral identified in the talcum powder products is asbestiform or non-asbestiform.

United States Environmental Protection Agency (EPA)

Multiple regulations from the EPA also recognize that "Asbestos means the *asbestiform* varieties of serpentine (chrysotile), riebeckite (crocidolite), cummingtonite-grunerite, anthophyllite, and actinolite-tremolite." National Emission Standards for Hazardous Air Pollutants, 40 C.F.R.§61.141 (2018); *see also* Toxic Substances Control Act – Prohibition of the Manufacture, Importation, Processing, and Distribution in Commerce of Certain Asbestos-Containing Products, 40 C.F.R.§763.163 (2018); Toxic Substances Control Act – Asbestos Containing Materials in Schools, 40 C.F.R.§763.83 (2018).

Likewise, as discussed above, EPA publications that contain test methods for the determination of asbestos in building materials define asbestos as those minerals with an asbestiform morphology. These definitions also state that the very properties of the asbestiform habit are what caused asbestos "to be widely used commercially," including "1) its ability to be separated into long, thin, flexible fibers; 2) high tensile strength; 3) low thermal and electrical conductivity; 4) high mechanical and chemical durability, and 5) high heat resistance." R.L. Perkins & B.W. Harvey, *supra*.

United States Department of Labor: Mine Safety and Health Administration

The mission of the Mine Safety and Health Administration (MSHA) is to "promote safe and healthful workplaces for U.S. miners." MSHA Mission, https://www.msha.gov. Like the EPA and OSHA, MSHA regulations define asbestos as "a generic term for a number of *asbestiform* hydrated silicates that, when crushed or processed, separate into flexible fibers made up of fibrils." 30 C.F.R.§71.702 (2018) (emphasis added). In fact, as is the case with OSHA, MSHA regulations pertaining to asbestos "[do] not include nonfibrous or non-asbestiform minerals." 73 Fed. Reg. 11284, 11292 (Feb. 29, 2008).

United States Geological Survey

The definition of asbestos provided by the United States Geological Survey (USGS) is discussed briefly here, as it is already covered in detail in the introduction section. The USGS is consistent with other federal

agencies in its definition. It notes that "the term 'asbestos' is not a mineralogical definition" and that, while "other minerals are similar to asbestos in their particle shape,… they do not possess the characteristics required to classify them as asbestos." USGS Facts About Asbestos. The USGS has also stated that "when it comes to health risk, it matter[s] whether an amphibole is asbestiform" because "the available evidence supports a conclusion that exposure to non-asbestiform cleavage fragments is not likely to produce a significant risk of developing asbestos-related disease." U.S. Geological Survey, *Some Facts About Asbestos* 2 (2001) (quoting 57 Fed. Reg. 24, 310).

National Institute for Occupational Health and Safety

The mission of the National Institute for Occupational Health and Safety (NIOSH) is to "develop new knowledge in the field of occupational safety and health and to transfer that knowledge into practice." About NIOSH, https://www.cdc.gov. NIOSH is part of the Center for Disease Control and Prevention. *Id.* Importantly, NIOSH states that "minerals with the same name may occur in a variety of forms called 'habits.'" Paul Middendorf, Ralph Zumwalde, & Robert Castellan, *Asbestos and Other Mineral Fibers: A Roadmap for Scientific Research,* NIOSH Mineral Fibers Work Group 2 (2007). NIOSH notes that the "[t]he mineralogical terms applied to habits are generally descriptive," and that the habits "important to asbestos and related minerals include fibrous, massive, prismatic, acicular, *asbestiform*, tabular, and platy." *Id.* Consistent with the other agencies discussed here, NIOSH defines asbestos as "a generic commercial term for a number of silicate minerals occurring in the asbestiform habit." *Id.* NIOSH has also stated that it "wishes to make clear that such non-asbestiform minerals are not 'asbestos' or 'asbestos mineral.'" *Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research,* Current Intelligence Bulletin 62, https://www.cdc.gov. NIOSH has also declared that only exposure to fibers from the asbestos minerals is credibly linked to adverse health effects in epidemiological studies. *Id.*

The United States Pharmacopeia and the Food and Drug Administration

There is an important relationship between the United States Pharmacopeia (USP) and the Food and Drug Administration (FDA). The FDA does not set its own definitional standards, but relies upon the standards, definitions, and testing methods set by the USP. The federal Food, Drug, and Cosmetic Act states that "[t]he term 'drug' means… articles recognized in the official United States Pharmacopœia….[and] [t]he term 'official compendium' means the official United States Pharmacopœia." 21 U.S.C.A.§321(g)(1), (j) (2016). The act continues to provide that "[a] drug or device shall be deemed to be *adulterated*…If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium." 21 U.S.C.A.§351(b) (2016) (emphasis added). Therefore, the FDA regulates drugs and devices as defined by the USP, and will find a drug or device adulterated, or contaminated, if it does not meet the standard set by the USP. This is critical to talc asbestos litigation, since the USP defines what constitutes talc, and this definition includes a test for the contamination of asbestos. This test is called an "Absence of Asbestos" test. Notably, to find the presence of asbestos, this test directs the one performing it to looks for particles that match the EPA R-93 definition of asbestiform:

> Procedure 3: The presence of asbestos… is shown if there is a range of length to width ratios of 20:1 to 100:1, or higher for fibers longer than 5µm; if there is a capability of splitting into very thin fibrils; and if there are two or more of the following four criteria: (1) parallel fibers occurring in bundles, (2) fiber bundles displaying frayed ends, (3) fibers in the form of thin needles, and (4) matted masses of individual fibers and/or fibers showing curvature.

USP, *Talc Revision Bulletin*, August 1, 2011, at 2, http://www.usp.org.

Likewise, the USP distributed a *stimuli* paper in 2014, meant to encourage debate and feedback from the scientific community. This paper defined asbestos as "a commercial/industrial term applied to certain naturally occurring minerals when these minerals crystallize in the asbestiform habit (generally defined as minerals with the growth form similar to commercial forms of asbestos)." L. Block, et. al., *Stimuli to the Revision Process; Modernization of Asbestos Testing in USP Talc*, U.S. Pharmacopeial Convention (2014),

> EPA publications that contain test methods for the determination of asbestos in building materials define asbestos as those minerals with an asbestiform morphology.

United States Consumer Product Safety Commission

The Consumer Product Safety Commission (CPSC) is an organization "with a mission to protect the public against unreasonable risks of injury or death from consumer products." https://www.cpsc.gov. In conjunction with a 1988 investigation into allegations of tremolite asbestos in children's play sand, the CPSC stated that "tremolite asbestos and tremolite cleavage fragments, however, are not a single type of material." *Briefing Package of the CPSC Office of the Secretary on a Petition to Ban Play Sand with Non-Asbestiform Tremolite,* U.S. Product Safety Commission (1988). The CPSC noted that while these two materials are "chemically similar, they are physically distinct." *Id.* Furthermore, the CPSC stated that "tremolite cleavage fragments are not asbestos, since a fibrous habit is necessary for a particle to be considered asbestos" and that "we know of no studies implicating tremolite cleavage fragments by themselves as a health hazard." *Id.*

American Society for Testing and Materials International

The American Society for Testing and Materials International (ASTM) is "one of the largest voluntary standards developing organizations in the world" and develops "technical documents that are the basis of manufacturing, management, procurement, codes and regulations for dozens of industry sectors." https://www.astm.org. There are several ASTM documents pertaining to asbestos and several ASTM test methods pertaining to the detection of asbestos. The ASTM defines asbestos as "a term applied to six naturally occurring minerals exploited commercially for their desirable physical properties, which are in part derived from their asbestiform habit." Malcolm Ross, Richard A. Kuntze, & Robert A. Clifton, *A Definition for Asbestos*, in Definitions for Asbestos and Other Health-Related Silicates, ASTM Special Technical Publication 834, 140,139-147, (B. Levadie, ed., 1984). Two common ASTM test methods that are encountered in asbestos litigation, D5755-09 and D6281-09, also define asbestos by asbestiform habit.

The D5755-09 method defines asbestos as follows:

> 3.1.2 *asbestos*—a collective term that describes a group of naturally occurring, inorganic, highly fibrous, silicate dominated minerals, which are easily separated into long, thin flexible fibers when crushed or processed.
>
> 3.1.2.1 *Discussion*—Included in the definition are the asbestiform varieties of…

Standard Test Method for Microvacuum Sampling and Indirect Analysis of Dust by Transmission Electron Microscopy for Asbestos Structure Number Surface Loading. ASTM Designation D5755 - 09 (Reapproved 2014).

The D6281-09 method defines asbestos as follows:

> 3.2.3 *amphibole asbestos*—amphibole in an asbestiform habit.
>
> 3.2.6 *asbestos*—a collective term that describes a group of naturally occurring, inorganic, highly fibrous, silicate dominated minerals, which are easily separated into long, thin flexible fibers when crushed or processed.
>
> 3.2.6.1 *Discussion*—Included in the definition are the asbestiform varieties of…

Standard Test Method for Airborne Asbestos Concentration in Ambient and Indoor Atmospheres as Determined by Transmission Electron Microscopy Direct Transfer (TEM). ASTM Designation D6281-09 (2014).

■

Attorneys' should familiarize themselves with a rudimentary understanding of the following screening tools: x-ray diffraction testing, polarized light microscopy testing, transmission electron microscopy testing, the Blount method.

■

International Organization for Standardization

Similar to the ASTM, the International Organization for Standardization (ISO) is an organization that was created in order to "facilitate the international coordination and unification of industrial standards." https://www.iso.org/about-us.html. ISO testing standards for the identification of asbestos are frequently cited and used by experts in asbestos litigation. ISO methods also define amphibole asbestos as "[a]mphibole in an asbestiform habit" and define asbestiform as "a specific type of mineral fibrosity in which the fibers and fibrils possess high tensile strength and flexibility." ISO 10312 Ambient air—Determination of asbestos fibres—Direct-transfer transmission electron microscopy method, International Organization for Standardization, at 3.3, 3.5 (1st ed) (1995).

Defendants will frequently try to introduce as many of these definitions and standards as they can to a jury, since they tend to bolster the defense position that non-asbestiform minerals categorically cannot be asbestos. If the jury accepts this science, then the next fight in the litigation is whether the minerals in the talc at issue are in fact non-asbestiform.

Testing Methodologies and Counting Rules

Because the minerals at issue in talc asbestos litigation are microscopic, testing to determine the presence of asbestos or whether a mineral is asbestiform necessarily involves microscopy. There are two layers to each testing methodology: the tool used for the method, and the scientific technique used in that method.

Talc Testing with Various Microscopy Tools

Analysts can use various microscopy tools to determine whether a given mineral is present, and if present, the amount of a given mineral in a sample. Attorneys' should familiarize themselves with a rudimentary understanding of the following screening tools: x-ray diffraction testing, polarized light microscopy testing, transmission electron microscopy testing, the Blount method.

X-Ray Diffraction Testing (XRD)

X-ray powder diffraction (XRD) is a screening tool used to determine the presence and abundance of a given mineral in a bulk sample. Because it examines a larger amount of material than the microscopy techniques discussed below, it provides a better measurement of the full mineralogical composition of a talc sample, but is also less sensitive. Testing by XRD can establish the absence of amphibole or serpentine minerals, thus excluding the possibility of asbestos contamination to level of 0.10 percent by weight for tremolite. However, because XRD cannot show the "morphology," *i.e.*, the size or shape of particles identified, it cannot confirm whether any amphibole or serpentine found is the asbestiform or non-asbestiform variet-

ies of the minerals. *See* Arthur N. Rohl and Arthur M. Langer, *Identification and Quantitation of Asbestos in Talc*, 9 Envtl. Health Persp. 95 (1974).

Polarized Light Microscopy Testing

Polarized light microscopy (PLM) is a tool used to examine any component of a bulk sample visually to determine if it is fibrous and to identify the minerals present by analyzing certain optical properties of the particle of interest in plane and cross polarized light. The combination of XRD and PLM is the current FDA approved method of testing talcum powder for asbestos. *See* USP Talc Revision Bulletin, *supra*. The USP Talc Expert Panel noted in its recent *Stimuli to the Revision Process* (2014), cited above, that asbestos analysis by PLM is good for larger-sized products typical of personal care talc products.

PLM analysis allows an analyst to examine a population of particles and use several optical properties to determine both the mineral type and whether it is asbestiform. The EPA R-93 protocol, for instance, contains a table of optical properties for asbestos, listing the morphology, color, refractive indices, birefringence, extinction, and sign of elongation associated with each mineral—all of which must be measured and confirmed by PLM in order to identify asbestos correctly. R.L. Perkins & B.W. Harvey, *supra*, at 19.

Because PLM analysis examines a greater number of particles than transmission electron microscopy (TEM) analysis (explained below), examination of populations of particles is best performed by PLM. This position is also supported by the USGS, which states that since "long, thin cleavage fragments resemble asbestos fibers," an analyst should "compare the shapes of *several hundred amphibole particles* in the sample with those of asbestos reference materials and determine whether a sample is asbestiform with a fair degree of certainty." USGS Facts About Asbestos. However, the USGS cautions that "unless a fiber bundle has splaying ends, it is impossible to determine if a single long, thin particle grew that way (as asbestos) or is a cleavage fragment (non-asbestiform)." USGS Facts About Asbestos.

The Blount Method

One of the accepted methodologies to test for the presence of asbestos in talc is the Alice Blount method (the "Blount Method"). The Blount Method is a kind of concentration technique, where the samples of the material to be tested for the presence of asbestos (here, talc) are concentrated prior to examination through microscopy, allowing smaller concentrations of asbestos contamination to be detected.

The general procedure of the Blount Method involves "weighing about 60 mg sample into a microcentrifuge tube and adding heavy density liquid 2.810." Alice Blount, *Amphibole Content of Cosmetic and Pharmaceutical Talcs*, 94 Envtl. Health Persp. 225, 226 (1991). Then, "[a]fter these are mixed, the tube with the sample is placed in a vacuum for 3 min to remove the small bubbles adhering to the particles. After centrifuging the sample for 10 min at 7000 rpm, the heavy particles are removed from the bottom of the tube with a micropipette." *Id.* These particles are then counted in "20 FOV," a term that references the magnification used in PLM. *Id.*

Dr. Blount describes two methods by which the centrifuged heavy particles of talc may be prepared for microscopic analysis following the procedure above. These methods are selected depending on whether the counting is to be done on "a membrane filter (nuclepore, 1.0 um pore size) which has been placed on a microscope slid" or "as particles directly on a glass slide." *Id.*

To prepare the particles for counting on a membrane filter, Dr. Blount performs the following steps:

- "The heavy liquid with sample is forced through a membrane filter followed by distilled water to clean out the heavy liquid."
- "The filter is then placed on a glass slide while wet."
- "When dry, 1.584 refractive index liquid is placed on the filter followed by a cover glass."

To prepare the particles for counting directly on a glass slide, Dr. Blount performs the following steps:

- "The second case, particles directly on the microscope slide, requires transferring the heavy particles and some of the heavy liquid to a second centrifuge tube."
- "Distilled water is added and the sample is centrifuged."
- "The liquid is pipetted off and more distilled water added. This is repeated several times to clean out the heavy liquid."
- "Finally, the particles with several drops of water are transferred to a glass microscope slide."

Dr. Blount used the first method in her 1991 paper, taking photographs of the particles on a membrane filter on a glass slide. The membrane filter method is "good for analyzing amphiboles in talc," while the direct glass method allows for "any refractive index liquid [to] be used," allowing the analysis of "other mineral combinations, such as talc-quartz." *Id.*

TEM Testing

There are many different transmission electron microscopy (TEM) testing procedures, and TEM testing is required by several different organizations. For example, the ISO 10312 testing method for testing of ambient air for asbestos fibers calls for TEM. However, as defendants in talc litigation will point out, many of these testing procedures call for TEM in the context of asbestos abatement or other situations (such as school renovations), where asbestos is already known to be present or where an overabundance of caution is required. This is because TEM testing methods "cannot discriminate between individual fibres of the asbestos and non-asbestos analogues of the same amphibole mineral." ISO 10312 Ambient air—Determination of asbestos fibres—Direct-transfer transmission electron microscopy method, International Organization for Standardization (1st ed.) (1995). Furthermore, these methods warn that "asbestos is often found, not as single fibers, but as very complex, aggregated structures which may or may not be also aggregated with other particles." *Id.* For these reasons, "some fibres cannot be positively identified as asbestos, even though the measurements indicate that they *could* be asbestos." *Id.* (emphasis added).

Furthermore, while there is controversy over whether TEM should be used in the analysis of talc for asbestiform miner-

als, there is additional controversy over the preparation method for TEM analysis. Some plaintiffs' experts claim to use the Blount Method, which requires PLM, but then proceed to analyze the concentrated talc sample with TEM. Because TEM is not the same instrument as PLM, the membrane filter or direct glass preparation methods used by Dr. Blount cannot be used in TEM analysis. Rather, TEM samples must be prepared for analysis using either direct transfer or indirect transfer (discussed below).

Transmission electron microscopy has also been used for purposes of asbestos identification, most commonly in air and water samples. When testing talc for asbestos, TEM is often used with energy dispersive spectra (EDS), sometimes referred to as energy dispersive x-ray analysis (EDXA) and selected area electron diffraction (SAED). This combination is called analytical electron microscopy (AEM) and consists of a three-part analysis. The first is TEM, in which a beam of electrons is transmitted through a specimen, permitting imaging at higher magnifications than light microscopes like PLM, with the disadvantage that it is much more difficult to examine populations. The TEM image itself allows only an examination of morphology as typically used in asbestos analysis.

A second component of AEM is EDS, which is an analytical technique used to identify the elemental composition of a material. In this technique, electrons are used to excite the elements in a given particle, which causes the particle to emit x-rays with energies that correspond to the particle's elemental composition. Because each element in a particle has unique characteristic x-rays, the composition of a particle can thus be determined.

The third and final component of AEM analysis is selected area electron diffraction (SAED). To perform SAED analysis, the analyst aims an electron beam at a particle under examination, and as the electrons pass through the particle, the arrangement of atoms or crystal structure in the particle cause the electrons to "diffract," creating a diffraction pattern. The diffraction patterns observed are a function of the orientation of the particle to the electron beam, thus there are hundreds of possible electron diffraction patterns for any given crystalline particle. The most useful type of electron diffraction pattern is called a zone axis and, in most cases, requires manipulation of the particle. *See* Arthur N. Rohl and Arthur M. Langer, *Identification and Quantitation of Asbestos in Talc*, 9 Envtl. Health Persp. 95 (1974).

Direct and Indirect Transfer Preparation Methods

Both direct transfer and indirect transfer TEM methods deal with the preparation of

a grid, which is necessary for TEM analysis. "The direct method had originally been developed for estimating numerical concentration, whereas historically the indirect method had been developed for determining mass concentration." Celine Eypert-Blaison, *et al.*, *Comparison of Direct and Indirect Methods of Measuring Airborn Chrysotile Fibre Concentration,* 54 Ann. Occup. Hyg. 55, 56 (2010).

In the direct transfer method, a cellulose ester membrane is placed on a glass slide with its sampling surface facing upwards. The filter is then "collapsed" by depositing a few drops of a dimethylformamide (DMF) solution (35 percent DMF, 15 percent acetic acid, and 50 percent water) on it. The filter is then "etched" in an oxygen plasma oven. A carbon layer is then deposited on the filter. Then, the filter is unstuck from the glass slide. The carbon is then deposited in an "evaporator" that creates a vacuum. Finally, microscopic grids are placed over the filter, and the filter is dissolved in an acetone vapor. Following this procedure, all that should remain are the grid and the thin layer of carbon on which the sample is suspended. *Id.* at 57.

In the indirect transfer method, a cellulose ester sampling membrane is placed on a glass slide with its sampling surface in direct contract with the glass. The membrane and glass slide are then placed in a conical Pyrex tube, which is subsequently left in an oxygen plasma oven for two hours. This "ashes" the entire membrane. The calcination residue is retrieved by scraping the slide with a scraper. The residue is then put into a suspension in demineralized water, and that suspension is hand shaken. It then is filtered through either (1) a pre-carbonated filter or (2) another cellulose ester membrane. If using a pre-carbonated filter, a second carbon layer is deposited on the filter, after filtration through the pre-carbonated filter, such that the fibers and particles are suspended between two carbon layers. The pre-carbonated filter is then dissolved with chloroform, and the carbon layers are transferred to a microscope grid. If using another cellulose ester membrane, the analyst first must filter the suspension through a cellulose ester membrane with pores sized .22um; the rest of the procedure is the same as the direct method above. *Id.* at 57.

Thus, in the indirect transfer method, the sample undergoes a more rigorous transformation and the "main criticism of this indirect method is that fibre clusters can be separated during preparation; this would promote fibre release and thereby maximize the fibre number concentration." *Id.* Therefore, using indirect transfer TEM techniques may artificially inflate the asbestos concentrations reported in the final analysis by promoting fiber release within the sample. For example, the asbestos concentrations reported by samples prepared "using the indirect transmission electron microscopy (TEM) method" can be up to "15.5 times the mean obtained by using the direct TEM method." Chung-Yung Hwang, et. al., *Comparison of Methods of Assessing Asbestos Fiber Concentrations*, 38 Arch. Environ Health, 5. Such discrepancies in asbestos concentrations can result because "[t]he indirect sample transfer technique tends not only to break up fibre bundles and agglomerates but also gives a measure of the total mass of airborne asbestos, whereas direct transfer measures only the respirable fibres." Sahle W. & Laszlo H., *Airborne Inorganic Fibre Level Monitoring By Transmission Electron Microscope (TEM): Comparison Of Direct And Indirect Sample Transfer Methods*, 40 Ann. Occup. Hyg. 42 (1996).

It is critical for every party in talc litigation to pay close attention to expert discovery and the evidence code for their jurisdiction.

Counting Rules

Since TEM cannot determine whether a given particle of a mineral is asbestiform or non-asbestiform, TEM analysis determines whether something is considered asbestos by using counting rules. These rules count anything that fits their morphological criteria as asbestos. For example, the Asbestos Hazard Emergency Response Act (AHERA) contains counting rules that plaintiffs' experts frequently use in conjunction with their TEM testing. Although AHERA also defines asbestos as "the asbestiform varieties of" six the regulated minerals, the counting rules are based on TEM testing that cannot determine asbestiform habit. 40 C.F.R. §763.83. These counting rules state that "any continuous grouping of particles" with an "aspect ratio greater than or equal to 5:1 and a length greater than or equal to .5µm" shall be recorded as asbestos. 40 C.F.R. §Pt. 763, Subpt. E, App. A. These morphological standards are more inclusive than the USP and EPA definitions of asbestiform fibers addressed above, which require aspect rations of 20:1 or 100:1 or higher and a length of 5µm instead of 0.5µm, leading to more particles being identified as asbestos under these rules. Plaintiffs and plaintiffs' experts argue that these counting rules are the only proper method to determine whether a given particle is asbestos and that TEM testing is the best because it is most sensitive. In rebuttal, defendants and defense experts argue that these AHERA counting rules only apply to schools that have undergone abatement for the *known* presence of asbestos. They further argue that these counting rules are overbroad for that exact reason—earlier testing with PLM under AHERA confirmed the presence of asbestos, and TEM testing and counting rules are only appropriate tools to confirm the success of abatement and not whether a given particle is asbestiform or non-asbestiform.

Conclusion

This article serves as a primer for attorneys on this topic, which remains firmly in the realm of expert testimony, but which reaches the issue at the heart of every talc asbestos case. Therefore, it is critical for every party in talc litigation to pay close attention to expert discovery and the evidence code for their jurisdiction. Motions *in limine*, evidentiary objections, and hearings under the relevant evidence code to determine admissibility of expert testimony are powerful tools that can alter the outcome of a case.